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Strengthening Intellectual Property Rights Globally: Impact on India's Pharmaceutical Exports

Jaya Prakash Pradhan





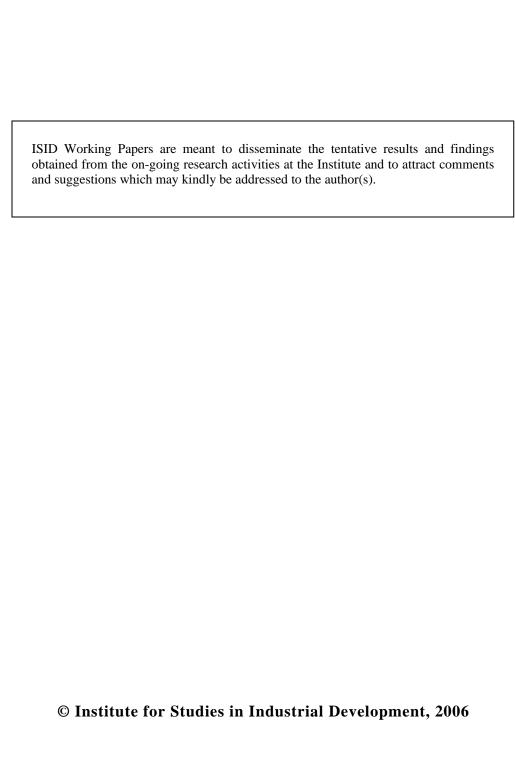
# Strengthening Intellectual Property Rights Globally: Impact on India's Pharmaceutical Exports

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#### Abstract

This paper examines the impact of a stronger protection regime for intellectual property on the exports of a technologically imitative country, India. The Indian experience in pharmaceutical exports would add value to the existing literature, which is otherwise largely limited to the experience of OECD countries and the USA. The empirical analysis presented here suggests that even an imitative developing country's exports need not be negatively affected by the strengthening of the patent regime globally and, in fact, in the case of pharmaceuticals, India stands to benefits from market expansion effects. However, this finding in the case of pharmaceutical products cannot be argued to hold for other sectors of the Indian economy and any generalizations of the overall impact of a stronger patent regime on aggregate exports from Indian economy must be based on individual sectoral studies.

#### JEL Classification

O31; F14

#### Keywords

Intellectual Property Rights; Pharmaceutical Exports

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# Strengthening Intellectual Property Rights Globally: Impact on India's Pharmaceutical Exports

Jaya Prakash Pradhan<sup>1</sup>

#### 1. Introduction

The emergence of global intellectual property protection regime (IPPR) based on the agreement on Trade-Related Intellectual Property Rights (TRIPS) has been a subject of considerable debate concerning its impact on international technology generation and transfers, FDI flows, trade performance and growth (see Maskus, 1998; Kumar, 2003 for surveys). For many developed countries in the European Union and the US the existing weak patent regime in many developing countries has been an important barrier for their exports. It is argued that the middle-income developing countries with their stronger imitative and reverse engineering abilities under low levels of patent protection not only reduce the exports flows from developed countries into their respective markets, but also steal market in the third countries. Therefore, the global patent regime, which harmonizes patent protection regime across countries by enhancing the scope of patent rights and strengthens their enforcement, can be expected to reduce distortions and impediments to trade in the global market. Predictably, stronger patent regime is conducive to the exports of developed countries, which are technology creators rather than that of developing countries, which are technology followers, focusing largely on imitating technologies embodied in the exported goods of developed countries.

Recent studies on the experiences of the OECD and US tend to support the expectation that the stronger patent regime is helpful for developed countries' export performance. Maskus and Penubarti (1998) found that strengthening patent regime in developing countries, in particular those with significant imitative capabilities, would result in net expansion of OECD exports. Earlier, Ferrantino (1993) had observed a weak positive link between aggregate U.S. export and national membership in IPRs treaties. Most recently, Smith (1999) with more disaggregated industry-wise bilateral export data at state level has confirmed the substantial export expansion effect in the case of US economy.

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However, the impact of stronger patent regime on the exports of developing countries has not yet received any attention in the literature. Perhaps this is because of accepting un-tested assumption among researchers that stronger patent regime largely has a detrimental effect on the exports of technologically imitating developing countries when they lose market in hitherto weak patent following countries. The contribution of the present paper is to examine empirically how and to what extent the strengthening of patent regime globally would affect the export of a developing country like India in a knowledge-based industry, namely pharmaceuticals. The Indian pharmaceutical industry has been chosen mainly because it has been thriving on a soft patent regime followed by India since 1970 and has been one of the most important export-oriented sectors of the Indian manufacturing. Thus, export effect of strengthening patent regime globally can be expected to be most crucial for Indian pharmaceutical industry. Further, the role of patent protection is considered to be of vital importance in the case of pharmaceutical products and that is why pharmaceutical firms of developed countries have strongly lobbied in the past to include stronger patent rights for pharmaceutical products in their respective trade policies.

The present paper is organized as follows: Section 2 reviews the evolution of patent regime in India and its impact on the growth of pharmaceutical industry. Section 3 summarizes the modifications in the existing patent regime needed to be in conformity with the global patent regime visualized by the TRIPS agreement. Section 4 presents the empirical framework for examining the effect of stronger IPPR on India's pharmaceutical exports and discusses results obtained from the empirical analysis. Section 5 concludes the paper.

# 2. Indian Patent Regime and the Pharmaceutical Industry

#### 2.1 Evolution of the Indian Patent Regime

The evolution of Indian patent regime can be seen in two distinct phases. In the first phase covering the period 1948-70 the Patents and Designs Act 1911 inherited by India from the past colonial regime continues to remain in force with a few modifications such as amendment for including the provisions of compulsory licensing. The Act of 1911 provided for a comprehensive patent protection system for all inventions except those relating to atomic energy and granting exclusive right for a term of 16 years from the date of application (Kumar and Pradhan, 2003). However, in the meanwhile the need to change the patent regime was growing because of its negative impact on the indigenous technological development in Indian pharmaceutical industry and consequent high drugs prices in India.

Given the strong product patent regime, there was little international transfer of technology to the industry and most of the patent holding foreign companies were found to be engaged in merely importing bulk drugs and processing them into formulations. In many cases foreign firms taking advantage of the product patent in the Patent and Design Act have prevented Indian firms' efforts towards technological self-sufficiency. The celebrated case in which a German MNE, Farbwerke Hoechst, had prevented an Indian firm, Unichem Laboratories, from producing tolbutamide by a court judgment, along with many other cases had build up domestic pressures on Indian government in the late 1960s to shift to a soft patent regime (Desai, 1980).

A poor country like India, which had little technological base for making innovations during that phase found that the stronger patent regime guaranteeing a long-term monopoly for foreign inventors had not benefited the country. Due to the absence of domestic competition ensured by the patent regime, foreign firms continue to charge higher prices for their patented drugs, earning India a classic distinction of lower per capita income country with highest drugs prices in the world as observed by Kefauver Committee in 1961.

Against this backdrop India shifted to a new patent regime in 1970 and thus, marked the beginning of the second phase in the evolution of Indian patent regime. The Indian Patent Act, 1970, which came into force in 1972 provided product patents for all inventions except food, medicine, drugs and substances produced by chemical process. For the excluded category, only the process patent has been accorded. The patent term has been reduced from 16 years to 14 years and in the case of food, chemicals, pharmaceuticals and agrochemicals the patent duration has been made shortest to 5 years from the date of sealing or 7 years from the date of application, whichever occurs earlier. Space, atomic energy, agriculture and horticulture, biological materials and all life forms are excluded from the scope of patent protection. Further, the Act made it clear that the patented innovations must work in India on a commercial scale and that patent protection is not provided so as to allow the patentees to enjoy a monopoly by importing patented product. The provision of compulsory license after the expiry of three years from the date of sealing of a patent has been made on the ground of public health and accessibility.

Therefore, the new Patent Act of 1970 has radically changed the patent protection for pharmaceutical products by granting only process patent and that also for a very short duration. The fact that a pharmaceutical product can be produced by a variety of processes coupled with the provision of compulsory licensing after three years of patent sealing has considerably reduced the strength of patent protection in India.

#### 2.2 Performance of the Indian Pharmaceutical Industry

The change of patent regime in 1970 has been a turning point in the growth of Indian pharmaceutical industry. In the pre-1970 situation the Indian pharmaceutical industry hardly had any technological base to start local production and it was largely importing bulk drugs to process them into formulations. Foreign firms dominated the industries accounting for more than 75 percent of the domestic pharmaceutical market and were reluctant to translate their patent enjoyed under the Patent Act of 1911 into local production. This forced the government to directly intervene in the production of important bulk drugs such as antibiotics by setting up of public sector units such as Hindustan Antibiotics Ltd (HAL) in 1954 and Indian Drugs and Pharmaceuticals Ltd (IDPL) in 1961.

Following the adoption of Indian Patent Act 1970 along with several Drugs and Pricing Policies and Foreign Exchange Regulation Act, the industry had seen remarkable transformations in production, technology and trade (see Kumar and Pradhan, 2003 for details about these policies). In the 1980s the industry had grown at a rapid rate of 11 percent per year, which further accelerated to 17 percent per annum during 1990s. The value of production, which was merely Rs. 168 crore in 1965-66 has risen by nearly thirteen times to Rs. 19, 737 crore in 1999-2000 (Table-1).

This high growth performance of the industry can be partly attributed to the soft patent regime, which had boosted local innovation mainly in the form of adaptation, reverse engineering and new process developments. The industry had achieved a near self-sufficiency in raw materials to start production from as basic stage as possible and achieved a high degree of self-sufficiency with regard to its requirements of basic raw materials and intermediates. The production of bulk drugs has grown at the same rate with the production of formulations in the 1980s but has out-paced that of formulations during the nineties. As a result, the share of bulk drugs in the total production has increased from 11 percent in 1965-66 to 19 percent in 1999-2000 (Table-1). In 1991, about 70 percent of the domestic pharmaceutical market was accounted by the domestic firms in the case of bulk drugs and 80 percent in the case of formulations (Lanjouw, 1998) indicating significant reduction in the role of foreign firms in Indian pharmaceutical industry between pre-1970 and 1990s situation.

Table 1
Production in the Indian Pharmaceutical Industry, 1965-66 to 1999-2000

Year	Production (Rs. Crore)			% share of
	Bulk Drugs	Formulations	Total	bulk drugs
1948	-	10	10	-
1965-66	18	150	168	10.7
1980-81	240	1200	1440	16.7
1981-82	289	1434	1723	16.8
1982-83	345	1660	2005	17.2
1983-84	355	1760	2115	16.8
1984-85	377	1827	2204	17.1
1985-86	416	1945	2361	17.6
1986-87	458	2140	2598	17.6
1987-88	480	2350	2830	17.0
1988-89	550	3150	3700	14.9
1989-90	640	3420	4060	15.8
1990-91	730	3840	4570	16.0
1991-92	900	4800	5700	15.8
1992-93	1150	6000	7150	16.1
1993-94	1320	6900	8220	16.1
1994-95	1518	7935	9453	16.1
1995-96	1922	9125	11047	17.4
1996-97	2186	10494	12680	17.2
1997-98	2623	12068	14691	17.9
1998-99	3148	13878	17026	18.5
1999-2000	3777	15960	19737	19.1
	Сотроипа	Growth Rate (%	(6)	-
Period	Bulk Drugs	Formulations	7	otal
1980-81 to 1989-90	10.28	11.19	1	1.05
1990-91 to 1999-00	19.49	16.42	1	6.95

Note: Compound growth rate has been calculated from semi-log regression model. Sources: Department of Chemicals and Petrochemicals, various Annual Reports and Organization of Pharmaceutical Producers of India

The growing technological strength of Indian pharmaceutical industry has translated into its high trade performance during 1990s with a consistently growing trade surplus (Table-2). The situation was quite opposite in the 1970s when India had to import large quantities of essential drugs and intermediates to meet its domestic demand in excess of its exports and thus consistently had seen unfavorable trade balance in pharmaceutical products. The pharmaceutical exports from India have been consistently growing at

much higher rate than the total exports since 1970s, increasing the share of pharmaceutical products in Indian's total export from mere 0.6 percent in 1970-71 to 4 percent in 1999-2000 (Table-2). India has been benefiting from revealed comparative advantage in pharmaceutical product as India's share in world pharmaceutical exports remain much higher than her share in world merchandized exports.

Regionally, the pharmaceutical export from India is more destined to developing countries and they account for about 56 percent of the total pharmaceutical exports during 1996-1999 (Table-3). With about 29 percent share, developed countries stand as the second important export destination followed by Central and Eastern European countries with 12 percent share. Within developing countries, Asia and Pacific countries emerged as the most important export destinations (36 percent). Table-4 provides the top fifteen export destinations of Indian pharmaceutical exports. Clearly, these top fifteen countries together account for about 60 percent of the total pharmaceutical exports from India indicating that major export market for Indian pharmaceutical products are geographically concentrated in these countries. Russia, USA, Hong Kong, and Germany are the top four export destinations.

#### 3. TRIPS and the Indian Patent Regime

The existing Indian Patent Act 1970 will have to undergo radical transformations to meet India's obligation under the TRIPS agreement. First, Indian patent regime has to recognize product patent in chemical industry including pharmaceuticals, which is hitherto granted only process patent under the Act of 1970. Second, it has to expand scope of patent rights to include patent for micro-organisms and protection of plant varieties either by the provision of sui generic system or by any combination thereof. Third, the duration of patent term has to increase from existing 14 years to 20 years in general and in the case of food, chemicals, pharmaceuticals and agrochemicals from exiting 7 years to 20 years. Under TRIPS, the working of the patent has been expanded to include the importation of the patented product and the burden of proof has been reversed in the case of a process patent. Although compulsory licensing is permitted under TRIPS, it comes with several restrictions.

Table 2 India's Trade in Pharmaceutical Products, 1970-71 to 1999-2000

Year	Year Trade in medicinal and pharmaceutical products (Rs. Crore)		As a percentage share of total	
	Exports	Imports	Trade balance	exports
1970-71	8.5	24.3	-15.8	0.55
1971-72	9.6	26.6	-17	0.60
1972-73	10.3	23.2	-12.9	0.52
1973-74	15.1	26.4	-11.3	0.60
1974-75	23	34.2	-11.2	0.69
1975-76	22.2	36.3	-14.1	0.55
1976-77	24.2	42.2	-18	0.47
1977-78	31.2	63.6	-32.4	0.58
1978-79	56.5	79.2	-22.7	0.99
1979-80	87.5	73.9	13.6	1.36
1980-81	67.4	84.6	-17.2	1.00
1981-82	122	84.4	37.6	1.56
1982-83	112.2	88.8	23.4	1.27
1983-84	155.2	146.9	8.3	1.59
1984-85	234.2	137.1	97.1	1.99
1985-86	157.9	177.2	-19.3	1.45
1986-87	161.3	213.8	-52.5	1.30
1987-88	326.1	167.8	158.3	2.08
1988-89	473.7	236.4	237.3	2.34
1989-90	849.6	399.7	449.9	3.07
1990-91	1014.1	468.4	545.7	3.11
1991-92	1550.1	558.5	991.6	3.52
1992-93	1533	813.2	719.8	2.86
1993-94	2009.7	808.8	1200.9	2.88
1994-95	2512.3	937.2	1575.1	3.04
1995-96	3408.7	1358	2050.7	3.21
1996-97	4341.8	1089.2	3252.6	3.65
1997-98	5419.3	1447.1	3972.2	4.17
1998-99	6256.07	1615.2	4640.87	4.48
1999-2000	6631.45	1502.3	5129.15	4.07
	Сотр	ound Growth Rate	(%)	
Period	India's pharma	iceuticaleExports	India's to	otal exports
1970-71 to 1979-80	27	7.68	19	9.31
1980-81 to 1989-90	25	5.41	14.92	
1990-91 to 1999-00	24	4.08		9.11

Note: Compound growth rate has been calculated from semi-log regression model. Source: RBI (2000), Handbook of Statistics on Indian Economy, Bombay: Reserve Bank of India.

Table 3
Geography of India's Pharmaceutical Exports, Cumulative Flows over 1996-99

Region	Value ( In \$ 000)	% share
Developed countries	1085300	29.2
Western Europe	678850	18.2
North America	330281	8.9
Other developed countries	76169	2.0
Developing countries	2084315	56.0
Africa	543922	14.6
Latin America and the Caribbean	194867	5.2
Asia and the Pacific	1345526	36.2
Central and Eastern Europe	443056	11.9
Others	107608	2.9
World	3720279	100
Source: Author's estimation based on Tr	ade Analysis System, I	JNCTAD.

Table 4
Indian Pharmaceutical Exports by Top Fifteen Destinations over 1996-99

		ch Destinations over 1990-	
Country	Export (In \$ 000)	% share to total export	Rank
Russian Federation	359123	9.7	1
United States	296995	8.0	2
China, Hong Kong SAR	254279	6.8	3
Germany	201174	5.4	4
Nigeria	185302	5.0	5
The Netherlands	131412	3.5	6
Viet Nam	120088	3.2	7
United Kingdom	109643	2.9	8
Sri Lanka	107713	2.9	9
Nepal	92552	2.5	10
China	91216	2.5	11
Singapore	79155	2.1	12
Iran, Islamic Republic of	71338	1.9	13
Italy	58122	1.6	14
Thailand	56311	1.5	15
Sum total of top fifteen	2214423	59.5	
Source: Author's estimation based on Trade Analysis System, UNCTAD.			

There have been several studies on how these changes in Indian patent regime may affect the Indian pharmaceutical industry, health security of Indian masses and development in developing countries in general (Dhar and Rao, 1992; Nayyar, 1992; Mashelkar, 2001; Mishra, 2001; Kumar and Pradhan, 2003 and several others). Without repeating those implications, it may be stated here that the minimal patent protection as postulated by

TRIPS is going to institute dramatic changes in the patent regime of India and the world as well. When all WTO member countries get shifted to TRIPS regime then global patent regime is undoubtedly going to be more comprehensive and stronger than what it has been in the past. By January 2005 Indian patent regime needs to get shifted to the one visualized by TRIPS and there has already been several policy initiatives towards that. The 1999 Amendment has already provided for exclusive marketing rights (EMRs) as interim mechanism to shift to product patent. A bill for Second Amendment to the Indian Patent Act 1970 to extend the term of patents to 20 years is in the Parliament.

# 4. Impact of a Stronger Patent Regime on India's Pharmaceutical Exports

#### 4.1 A Framework of Analysis

In this section, we will develop an appropriate empirical framework to test the impact of stronger patent regime on India's pharmaceutical exports. As discussed in the introductory section, the level of patent protection can be an important factor to affect the level of Indian pharmaceutical exports into destination countries. Other things being equal, one would expect that increasing patent protection in importing countries may restrict pharmaceutical exports. This reduction would be directly proportional to the share of patented products in the total pharmaceutical products that Indian companies export to countries having weak patent regimes. Besides the level of patent protection in the destination countries, Indian pharmaceutical exports depend upon several factors characterizing the importing countries.

#### The Gravity Variables

One set of factors identified in the empirical framework is related to the gravity models of international trade. In its simplest form, gravity model predicts that the bilateral trade volume depends positively on the product of two countries' domestic product (GDP) and negatively on the distance between them. While the GDP of the exporting and importing countries are respectively interpreted as their production and absorption capacities, the distance is taken as a proxy for transaction and trade costs. The distance in gravity models, which is initially measured by physical distance, has recently been expanded to include cultural distance (proxied by common language) and common border. These gravity variables, namely GDPs and distances have been found to take account of a reasonable proportion of variation in the volume of trade over country-pairs and across time (e.g. Deardorff, 1984; Leamer and Levinsohn, 1995). The theoretical foundation for gravity formulation has been shown to derive from models of new trade theory in the 1980s (Helpman and Krugman, 1985; Helpman, 1987; Bergstrand, 1989) and

developments in neoclassical trade theory (Deardorff, 1998) that assumes full specialization of countries in differentiated products. This full specialization can be due to the structure of demand, economies of scale, cross-country technological differences, or differences in factor endowments (Feenstra, Markusen and Rose, 1998, 2001).

The adoption of gravity variables in our empirical framework needs modification as we are concerned with cross-country distribution of India's pharmaceutical exports. Since the focus is on one side of trade flows, namely export from India to other countries and not the product of the exports of two trading partners, only the GDP of the importing countries have been included in the empirical specification of the model. Higher the GDP of an importing country, one would expect more pharmaceutical exports into that country because of a higher absorptive capacity. Physical distance can also affect Indian pharmaceutical exports. The literature indicates that the impact of distance on bilateral trade is significantly increasing over time (Leamer and Levinsohn, 1995; Brun et al., 2005). Other things being equal, India can gain from exporting to nearby countries rather than far off, simply because of relatively lower transportation costs. Cultural distance may also affect export flows. A common language and culture can reduce transaction costs involved in trade. Language similarity brings cultural closeness, ensures ability to directly communicate and may improve understanding of Indian exporters on the foreign markets concern. The studies of Frankel (1997) and Melitz (2002) have confirmed that language plays an important role in trade. Hence, a positive relationship can be expected between Indian pharmaceutical exports and common language dummy. Exports may also be subjected to border effects. Sharing a common border or not (country adjacency dummy) may involve several political and security costs like problems of immigration, security and border hostilities. For example, India has problems with its neighbors like Bangladesh and Pakistan, US with Mexico, and Ukraine with Russia, etc. Most of the time, these issues turn political on the domestic front and affect the overall economic transaction between countries. Although, a common border can be expected to boost trade between trading partners under a regime of cordial bilateral relationship, this may not hold true in many cases where relations are not friendly. Helpman, Melitz and Rubinstein (2005) have observed that the effect of a common border can be trade suppressing between neighbors if there exists territorial border conflicts.

#### The Trading Blocks Variables

The membership status of the importing country in regional trading blocks can also be an important determinant of India's pharmaceutical exports across countries. Empirical studies have confirmed the role of trading blocks in shaping the world trade (e.g., see

Frankel, 1997). The trading block tends to affect the volume of trade between countries because it involves effects of trade creation and diversion. If both the trading partners are members of the same trading arrangement then their trade can be expected to expand whereas trade between a member-country and non-member country is likely to contract. Members of a trading block grant each other a host of preferences in terms of tax, tariff, and investment, which are not available to a non-member. To capture the effect of regional trading arrangements on India's pharmaceutical exports a group of trading blocks dummies were included in the model. These trading blocks are- European Union, North American Free Trade Agreement, Latin American Free Trade Association and Latin American Integration Association, Association of Southeast Asian Nations, Asia Pacific Economic Cooperation, and South Asian Association for Regional Cooperation.

#### Prices and Exchange Rate

Studies have also suggested that bilateral trade volume may also depend on other variables like price level (e.g., Bergstrand, 1985) and exchange rate (e.g., López-Córdova and Meissner, 2003). A pair of countries sharing a common exchange regime or having stable exchange rates tends to trade more with each other. In the present study we postulate that depreciation of foreign currency would impact negatively on India's pharmaceutical exports by making it costlier in the importing countries. We have also included the national price levels of the importing countries in the model. It is expected that importing countries with relatively higher prices would attract more exports from India than those with relatively lower prices.

Taking account of the above mentioned three sets of independent variables, namely gravity, trading block, exchange rate and price variables, and incorporating the index of patent rights, the empirical model we intend to test in the present study takes the following form:

#### 5. The Model

$$LogEXPOR_{j} = \alpha + \beta_{1}LogGDP_{j} + \beta_{2}LogGDPPC_{j} + \beta_{3}LogDIST + \beta_{4}ADJ + \beta_{5}LAN$$

$$+ \beta_{6}LogEXR_{j} + \beta_{7}LogPRICE_{j} + \beta_{8}D_{E}U + \beta_{9}D_{NA}FTA + \beta_{10}D_{L}AT$$

$$+ \beta_{11}D_{ASEAN} + \beta_{12}D_{APEC} + \beta_{13}D_{SAARC} + \beta_{14}IPR + u$$
(1)

Where: LogExport<sub>j</sub> = (Log of) India's pharmaceutical exports to *j*th country in \$ 000.

 $LogGDP_j = (Log of) GDP of jth country in $000.$ 

 $LogGDPPC_j = (Log of) Per capita GDP of jth country in $000.$ 

 $LogDist_i = (Log of)$  Distance between India and *j*th country in kilometers.

- ADJ = A dummy variable taking 1 in case *j*th country share a common border with India, zero otherwise.
- LAN = A dummy variable taking 1 in case *j*th country share a common language with India, zero otherwise.

LogEXR= (Log of) Local currency per US \$

LogPRICE=(Log of) Price level

- D\_EU = A dummy variable taking 1 in case *j*th country is a member of European Union, zero otherwise.
- D\_NAFTA = A dummy variable taking 1 in case *j*th country is a member of the North American Free Trade Agreement (NAFTA), zero otherwise.
- D\_LAT = A dummy variable taking 1 in case *j*th country is a member of the Latin American Free Trade Association and Latin American Integration Association, zero otherwise.
- D\_ASEAN = A dummy variable taking 1 in case *j*th country is a member of the Association of Southeast Asian Nations (ASEAN), zero otherwise.
- D\_APEC = A dummy variable taking 1 in case *j*th country is a member of the Asia Pacific Economic Cooperation (APEC), zero otherwise.
- D\_SAARC = A dummy variable taking 1 in case *j*th country is a member of the South Asian Association for Regional Cooperation (SAARC), zero otherwise.

IPR = The Index of Patent Rights Constructed by Ginarte and Park (1997) u = the error term.

#### 5.1 Data Sources and Methods of Estimation

The empirical estimation of the model formulated above is conducted with data collected from a variety of sources. The data on India's pharmaceutical exports at 5-digit level of Standard International Trade Classification (SITC) Rev 3 to a total of 106 countries over 1996-1999 has been extracted from the Trade Analysis System of the UNCTAD. After obtaining, the data all the 5-digit pharmaceutical products are added to obtain the total pharmaceutical exports from India (see Appendix for the list of pharmaceutical products, along with their product code and description). The dependent variable is the cumulative pharmaceutical export flows of India over 1996-1999. The purchasing power parity (PPP) GDP and per capita GDP for the year 1999 has been obtained from World Development Indicator CD-ROM, World Bank.

The data on distance and common language has been collected from the Centre D'Etudes Prospectives Et D'Informations Internationales (CEPPII). The CEPPII dataset calculates bilateral distances following the great circle formula that utilized latitudes and longitudes of the most important city (in terms of population) or of its official capital. The dataset provides several language variables like the official languages (up to three), the

languages spoken by at least 20% of the population and the languages spoken by between 9% and 20% of the population (up to four languages in each of those cases). For India, the dataset reports both English and Hindi as the official languages as well as those spoken by 20% population. For measuring language proximity we have taken English as the official language of India and constructed the desired language dummy. Information on exchange rate (local currency per US \$) for the year 1999 has been collected from the CD-ROM International Financial Statistics, November 2005, International Monetary Fund. The price level used in the study is the GDP deflator obtained by dividing the current price GDP to constant price GDP and multiplying by 100. The current and constant GDPs are collected from World Development Indicator CD-ROM, World Bank.

The data on patent index for the year 1995 has been drawn from the updated patent right index provided by W.G. Park and S. Wagh in the Economic Freedom of the World: 2002 Annual Report and the Fraser Institute (2004). The Ginarte and Park patent right index ranges from 0 to 5, with higher number indicating higher degrees of patent protection (see, Ginarte and Park, 1997, for more details). The index has been constructed by aggregating a country's performance in five equally-weighted categories such as the extent of patent coverage, the length of patent protection, enforcement mechanisms, restrictions or limitations on the use of patent rights, and membership in international patent treaties.

The gravity model (1) has been estimated with the OLS regression analysis with robust standard errors obtained from the STATA statistical package. The robust standard errors are those that corrected for the problem of heteroscedasticity normally encountered in a cross-sectional analysis like the present one. Along with estimating the unstandardized coefficients, the study has also estimated the fully standardized coefficients popularly known as  $\beta$  coefficients to determine the relative strength of independent variables in explaining India's pharmaceutical exports. Further, the estimated model has been statistically simulated to evaluate the export responsiveness to different levels of patent protection.

#### 5.2 Empirical Results

Table-5 summarizes the results obtained from OLS estimation of the augmented gravity model. In terms of F-test the estimated model is highly significant and explains about 62 percent of variation in the (log) pharmaceutical exports of India. Majority of the standard gravity factors such as GDP, distance and common language have come out with significant effects on Indian pharmaceutical exports and which are in conformity with

earlier gravity studies on bilateral trade flows. The estimation shows that India's pharmaceutical exports depend positively on the overall economic size (proxied by GDP) of her trading partners but negatively with their income level (proxied by per capita GDP). This may be because the larger chunk of India's pharmaceutical exports consists of bulk drugs, which are sensitive to the overall market size rather than to the trading partner's income level. Therefore, with higher per capita income, countries may be shifting their import preference towards formulations which are more sensitive to the income level. Another reason could be that with higher per capita income households in the importing countries may prefer branded medical products that are supplied by the pharmaceutical producers from rich countries and thus reducing demand for generics sold by their Indian counterparts.

The distance variable has come up with a significantly negative impact on trade. This upholds the hypothesis that Indian pharmaceutical firms tend to export more if importing countries are situated nearer on a geographical scale. The dummy for common border has a negative effect that is statistically different from zero. This negative sign of the variable may have been due to the geo-political situations and security concerns that India has with her neighbors for a long time. From this it follows that a common border may not necessarily enhance exports as presumed generally and may reduce exports if a country has largely un-cordial bilateral relationships with her neighbors.

The common language dummy has a predicted positive sign and is statistically significant. Indian pharmaceutical exports, thus, appear to be more for those countries that speaks same language. The exchange rate is significant with the hypothesized negative sign. This finding, thus, suggests that importing countries with depreciation in their currencies lower their domestic demand for Indian exports. Depreciation discriminates against importing goods by making them more costly than before to the domestic consumers. The national price level, although has a negative coefficient, is not significantly different from zero. This would imply that national price levels in the importing countries are not a dominating factor affecting the Indian pharmaceutical exports; once we take into account the effect of other casual factors. The main reason for this finding may be the price inelasticity that exists in the pharmaceutical market, particularly for essential drugs.

Table 5
Impact of Patent Rights on India's Pharmaceutical Exports

	Variable: Log of Pharmacei	, ,		
Independent Variables	Coefficients	Fully standardi	zed coefficient	
	(t- value)	Value	Rank	
LogGDP	0.60011232***	0.6004	1	
LogGD1	(5.41)	0.0004	1	
LogGDPPC	-0.68780103***	-0.4523	2	
LogGDTTC	(3.27)	-0.4323		
LogDIST	-1.34117338***	-0.4424	3	
LogDIST	(4.39)	-0.4424	<u> </u>	
ADJ	-1.25505505***	-0.2663	5	
ADJ	(3.87)	-0.2003		
LAN	0.50543438***	0.2745	1	
LAIN	(4.13)	0.2/40	4	
LogEXR	-0.09338606*	-0.1402	9	
LUSUAK	(1.75)	-0.1402	9	
LogPRICE	-0.46746804	-0.043	10	
LOGI KICE	(0.64)	-0.043	12	
D_EU	0.20157017	0.0873	11	
D_E0	(0.79)	0.0073	11	
D_NAFTA	0.12154038	0.0258	14	
D_NAFIA	(0.55)			
D_LAT	0.51153647**	0.1996	6	
D_LA1	(2.19)	0.1990	O	
D_ASEAN	0.12113379	0.0358	13	
D_AULAIN	(0.45)	0.0550	10	
D_APEC	0.23853496	0.1093	10	
D_ALEC	(1.09)	0.1093	10	
D_SAARC	0.64887780***	0.1582	8	
D_SAARC	(4.04)	0.1362	O	
IPR	0.15502955**	0.1791	7	
II IX	(2.46)	0.1/ 71	/	
Constant	5.29054212**			
Constant	(2.33)			
F( 14, 91)	10.42			
Prob > F	0.0000			
Observations	106		5 1 1 1 1 1 1 1	
R-squared	0.62			
	e in paranthasas: * signific	cant at 100/ ** signific	: 	

*Notes*: Robust t-statistics in parentheses; \* significant at 10%, \*\* significant at 5%, \*\*\* significant at 1%; rank is based on the absolute value of the fully-standardized coefficients.

Among trading blocks only two, namely Latin American and SAARC, blocks turn out to be significantly positive indicating that they have been conducive to Indian pharmaceutical exports. The positive impact of Latin American dummy can be understood by the fact that Latin America has been an important export market for the Indian pharmaceutical firms. It is estimated that drugs, pharmaceuticals and fine chemicals account for about 27.8 per cent of the total Indian exports to the Mercosur region in 2000-01 (Exim Bank, 2002). India's presence in the Mercosur region through foreign direct investment (FDI) or through joint ventures (JVs) has been concentrated mainly in the pharmaceutical sector<sup>2</sup>. The FDI/IV provides Indian pharmaceutical firms the required insider status in the Latin America trading blocks and which may be helpful in more exports from home country in the form of raw materials, bulk drugs, technology, and skills. Moreover, India and the Mercosur trade block of Latin America have already signed a framework trade agreement to further improve trade between them. As postulated, India being a member of the SAARC block is benefiting from the trade creation effect generated by the trading block. The effect of other trading block dummies on Indian pharmaceutical exports have turned out to be statistically insignificant and thus indicate that relationship between these trading blocks and Indian pharmaceutical exports is not related significantly.

The performance of IPR variable is of primary interest here. The variable has come out with a positive effect and achieved a modest level of statistical significance. In terms of fully standardized coefficients, IPR is the seventh dominant explanatory factor influencing Indian pharmaceutical exports. This would suggest that increasing the level of patent protection overseas would significantly improve exports of pharmaceuticals from India. Therefore, this result tends to imply that even an imitative country like India, which had built its strength in pharmaceutical industry on the basis of a soft patent regime, may not necessarily loose export market in the face of strengthening patent regime globally, rather strong patent regime may be beneficial by enlarging its export market.

It is most likely that the effect of patent regime on the exports of a particular industry depends on the level of technological development that it has achieved relative to the

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<sup>&</sup>lt;sup>2</sup> Ranbaxy and Strides Arcolabs have joint ventures in São Paulo and Rio de Janeir, respectively. The Core Health Care/Claris Life Sciences have a subsidiary marketing their products in Sao Paulo. Strides Arcolabs started a factory in the State of Espirito Santo for manufacturing finished products. Torrent Pharmaceuticals, Aurobindo Pharma, Zydus Cadila and IPCA market or supply their bulk drugs or formulation to the Mercosur region. Many other Indian companies like Wockhardt, Unichem, Lupin Laboratories, NATCO and others are reportedly planning to set up their business operations in Brazil. See, Exim Bank (2002) for more details.

global technological frontier. The technological capabilities of Indian pharmaceutical enterprises are definitely at a lesser level than their developed countries counterparts but are not very far away. Indian pharmaceutical enterprises taking advantage of soft patent regime in the past have accumulated significant levels of technological development in terms of innovating new processes and new drugs delivery systems. In the late 1990s they demonstrated their capabilities to go for product developments by directing larger parts of their innovative activities for that purpose. The rising R&D and patenting activity of Indian pharmaceutical companies is indicating that innovation has become the most preferred business strategy for their survival. Given the fast pace at which Indian pharmaceutical industry is closing the technology gap with respect to global pharmaceutical industry, the emergence of new patent regime under TRIPS may be beneficial for its export performance. In fact, many Indian companies such as Dr. Reddy, Ranbaxy, and others are seeking stronger patent protection regime as they themselves are now becoming producers of new drug molecules.

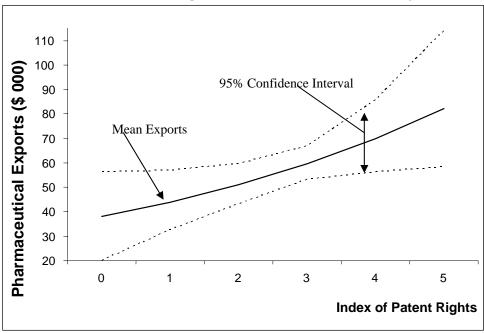
To determine the extent of export increase for different levels of patent protection statistical simulation has been undertaken and results obtained have been presented in Table-6 as well as shown in the Figure-1. Other things being equal, in the absence of patent rights (IPR=0) India would export about, on an average, \$38,000 of pharmaceuticals whereas in the face of providing maximum patent protection (IPR=5) globally India's export more than doubled to about \$82,000. Ceteris paribus, when global patent protection increases from its minimum value of zero to its maximum value of five it would result in net increase in the Indian pharmaceutical exports of about \$44,000. The 95-percent confidence interval around this increase in the mean value of pharmaceutical exports ranged from \$4,000 to \$89,000. The result is similar to the findings of Maskus and Penubarti (1998) and Smith (1999) that strengthening of the patent regime is associated with market expansion effect but with a crucial difference in that it has been observed in the case of a technologically imitative country like India.

Table 6
Results from Statistical Simulation of the Parameters

Situations	Quantity of Interest	Mean	Std. Error	[95% Conf. Interval]
Setting IPR=0	E[exp(LogEXPORT)]	38.14	8.10	[24.24 56.14]
Setting IPR=1	E[exp(LogEXPORT)]	43.98	6.18	[32.67 56.88]
Setting IPR=2	E[exp(LogEXPORT)]	51.09	4.13	[43.11 59.54]
Setting IPR=3	E[exp(LogEXPORT)]	59.49	3.51	[52.99 66.87]
Setting IPR=4	E[exp(LogEXPORT)]	69.75	7.43	[56.14 85.78]
Setting IPR=5	E[exp(LogEXPORT)]	82.22	14.41	[58.14 114.07]
Increasing IPR from 0 to 5	dE[exp(LogEXPORT)]	44.08	21.47	[3.77 89.57]

Notes: E[.] and dE[.] respectively denote expected value and change in expected value; Simulation has been done with the help of CLARIFY Software, Tomz, Wittenberg, and King (2002)

Figure 1
Mean Pharmaceutical Exports for Individual Values of Patent Rights



Source: Drawn based on Table-6.

#### 6. Conclusions

The existing literature on the impact of patent regime on exports has been largely confined to the experiences of developed countries in the OECD and the USA. Their empirical results strongly support the hypothesis that weak patent system existing in the more advanced countries of the developing part of the world economy act as a barrier to the exports of developed countries. It has been inferred that the strengthening of patent system in the developing countries with strong imitative countries such as China and India would result in market expansion for the products of developed countries.

The present paper studies the experience of an imitative country such as India and see how strengthening of patent regime on a global scale is going to affect its export performance. Indian pharmaceutical industry has been chosen as a fit case for the study as it has been growing under a soft patent regime since 1970 and hence the emergence of a stronger patent regime globally as visualized by the TRIPS can be expected to affect it significantly.

The analysis has been conducted in the framework of an augmented gravity model of bilateral trade flows in which intellectual property rights has been incorporated as another factor affecting India's exports to the host countries. The empirical results indicate that the strength of patent protection in the importing countries is an important factor affecting India's pharmaceutical exports. Higher the strength of patent protection higher is the export performance. Hence, it is clear that even the exports by a technologically imitative country depend positively on the strength of patent protection. However, this finding in the case of pharmaceutical products cannot be argued to hold true for other sectors of the Indian economy as different sectors differ in their level of technological developments relative to the global technological frontiers and hence any generalization on overall impact of stronger patent regime on aggregate exports from Indian economy must be based on further sectoral studies.

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# Appendix

# **List of Pharmaceutical Products**

SITC Rev	Description
3 Product	_
Code	
54111	Provitamins, unmixed
54113	Vitamins B, etc.unmixed
54114	Vitamin C, etc.unmixed
54115	Vitamin E, etc.unmixed
54116	Oth.vitamins etc.unmixed
54117	Mxt.provitamins,vitamins
54131	Penicillins etc.
54132	Streptomycins etc.
54133	Tetracyclines etc.
54139	Other antibiotics
54141	Alkaloids of opium etc.
54142	Alkaloids, cinchona etc.
54145	Theo-,aminophylline etc.
54147	Nicotine and its salts
54149	Oth.veg.alkaloid.etc.nes
54151	Insulin and its salts
54152	Pituitary hormones, etc.
54153	Adrenal cortical hormone
54159	Oth.hormone.etc.ex.gr542
54161	Glycosides, etc.

SITC Rev 3 Product Code	Description
54162	Glands,oth.orgns,etc.nes
54163	Antisera,etc., vaccines
54164	Blood;toxin,cultures etc
54191	Bandages,gauze,etc.nes
54193	Opacifying prep.xray exm
54199	Oth.pharmaceutical goods
54211	Med.penicilln,not retail
54212	Med.oth.antibio.not retl
54213	Med.penicillins,retail
54219	Med.oth.antibiotc,retail
54221	Med.insulin,not retail
54222	Med.oth.horm.,not retail
54223	Med.insulin,for retail
54224	Med.adrenal cortex,retl.
54229	Med.oth.hormones,retail
54231	Med.alkaloid,not retail
54232	Med.alkaloid,for retail
54291	Medicmnts,nes,not retail
54292	Med.vitamins etc. retail
54293	Medicmnts,nes,for retail

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