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TRIPS agreement: The Indian experience of pharmaceuticals industry and agriculture

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Abstract

Background/Objectives: To analyze the Pharmaceuticals and Agricultural sector of India which, before implementation of WTO'S TRIPS agreement, was able to develop cheap outputs by "riding-on" research and technological advancements of other nations.
Methods/Statistical analysis: The methodology of this study is descriptive in nature and therefore no statistical approaches have been used in majority of the paper except for digression into the analysis of IP protection on FDI inflows in the BIMSTEC countries. For that analysis linear OLS regression model has been employed and the results have been computed using E-Views. The major part of this study has been the data collection which has been sourced from CMIE, RBI, WIPO and DGCIS databases.
Findings: From 1990 to 2008, there has been a gradual rise in imports and exports of pharmaceutical products in India. However the share of Drugs and chemicals in the total exports has decreased after 2005, post TRIPs transition. Moreover the regression analysis of FDI inflows with IP protection shows that the countries tend to invest more in the countries with stronger intellectual property protection.
Application/Improvements: The models provided in way forward can very well be employed in any of the emerging and least developed countries. The models discussed are very much relevant for sub-African and African countries where the access to medicines and food is a major concern
***Keywords*:** TRIPS, WTO, Intellectual Property, Ginarte-Park, PIPP, Pharmaceuticals.

1. Introduction

Intellectual Property (IP) refers to any original human creation that has both commercial and moral value. In almost all fields of work - research, manufacturing, art, cinematography, art, commerce, science, etc.; there is a continuous need for innovation and new ideas. To persuade people to put efforts and finesse into development and innovation, they must be given an incentive and acknowledgment to their work and should be protected from piracy by giving some legal rights to these creations in the form of patents, copyrights, trademarks, geographical indications and industrial designs, etc.

1.1. TRIPs agreement and Uruguay round of negotiations

Under the Uruguay Round of trade negotiations (1994), World Trade Organization was established in the form of Marrakesh Agreement in which TRIPs (Trade-Related Aspects of Intellectual Property Rights) was annexed. TRIPs were aimed to make Intellectual Property Rights (IPRs) uniform at the global level. The Developing and Least-Developed countries (LDCs) were given a "transition period" till 2005 for implementation of TRIPs, which was later extended till 2016 for LDCs. Though Developing countries were granted exemption in the form of" transition period," the impact of TRIPS, however, has been argued to be ambivalent.

As it was a precondition to accept TRIPS, and India being the founding member of the WTO, accepted TRIPS agreement in 1995. The Indian patent regime under Indian Patents Act, 1970 was incompatible with the new provisions and hence required a lot of amendments. For many years before India became member of WTO, enjoyed a flexibility in patent regime as India did not recognize "Product" patents which was the reason that Indian Pharmaceuticals firms were able to produce cheap generic drugs and agriculture industry was able to make significant contributions to agriculture in the form of cheap agro-chemicals and high yield varieties of plants.

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1.2. Intellectual property rights

Intellectual property rights refer to the rights given to a person or a firm apropos of their creation. These rights usually give the creator an exclusive right over the use of the creation for a certain period. Part II of TRIPs agreement consists of seven sections dealing with intellectual property rights. Section 1 deals with copyrights and related rights, section 2 with trademarks, section 3 with geographical indications, section 4 with industrial designs, and section 5 with patents. Section 6 and 7 deals with layout designs of ICs (Integrated circuits) and protection of undisclosed information related to research, trade practices, etc.

Since this study focuses only on Pharmaceuticals industry and agriculture, I shall provide a detailed description of patents and patentability in the context of India.

1.3. A brief history of Indian patent laws

India became the signatory to TRIPs agreement in 1995 as it was one of the founding members of the WTO. The main motive for most of the developing countries accepting TRIPs was the hope of free flow of trade, investment and technical know from developed countries by the establishment of a uniform intellectual property regime. Moreover, this was the time when developing countries were also being favored in the dispute resolution process of the WTO, which gave them hope for new opportunities and access under the new regime.

1.4. Indian patents act, 1970

The Indian Patents Act, 1970 was the basic law in patent protection in India which had considerable restrictions in awarding patents to basic articles. It also restricted patent holders right to a considerable limit. It was a lengthy legislative process, and moreover, the applications for patents were considered from the socio-economic perspective also, especially in the fields of health and food.

Moreover, it only recognized process patents which were helpful for Indian pharmaceuticals and agro-chemical firms who were able to employ reverse engineering to track back production of drugs and chemicals and produce cheap generic drugs and other chemicals. The 1970 Patents act was altered three times in order to fully comply with the provisions laid down by the WTO's TRIPs agreement of 1995. The first and second amendment was incorporated in 1999 and 2002 respectively in order to include major provisions like extending patent protection for 20 years and granting EMRs (Exclusive Marketing Rights).The government also introduced the Protection of Plant Varieties and Farmers Rights (PPVFR, 2001) in 2001 in order protect new plant varieties It included”Right to Seed”, ”Right to Register Varieties” and establishment of National Gene Fund.

1.5. The patents (Amendment) Act, 2005 and India’s TRIPs+ Regime

The Patents (Amendment) Act, 2005 was India's final attempt to comply with the provisions laid by the TRIPs agreement, 1995. For developing and least developed nations, the deadline was the year 2000. However, under section 65.4 of TRIPs agreement, an additional transitional period of five years was awarded to all the economies which did not allow for product patents. Hence, India in 2004, through promulgation of an ordinance provided for product patents and 74 additional amendments to the Indian Patents Act, 1970. Technically, India had just to introduce the concept of product patents, but rather Indian government introduced a variety of alterations to the existing law which made India progressing into the TRIPs+ regime. The Patents (Amendment) Act, 2005 introduced a range of changes to the Indian patent regime which included the grant of ’product’ patents, exclusion of Swiss claim, deletion of EMR provisions and inclusion of software patentability.

The exclusion of Swiss claim and allowance of product patents were major provisions in the Patents (Amendment) Act, 2005 which transformed the Indian Pharmaceuticals and Agro-chemical industry. Before the allowance of ’product’ patents, Indian pharmaceuticals means the right to sell or distribute the article or substance covered in a patent or patent application in the country. EMRs will be granted when the there is no system of product patent in a country. It is only a temporary arrangement which will cease to have effect when product patent regime is introduced. Chemical firms were able to produce cheaper medicines as they were able to cut costs because of relatively lower investment in R&D. India developed into a world class generics industry.
In fact in 2002, India was the world's largest producer of generic drugs in terms of volume. The exclusion of the Swiss claim that is patent in respect of the use of a substance or composition that has already been used for a medical purpose for a new medical purpose shall not be granted.

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The 2005 Amendment Act amended the section 3(d) of the Patent act and introduced the concept of 'efficacy' which meant that mere discovery of a new form of a known substance does not add to enhancement in its property and thus cannot be patented. The term 'efficacy' though has not been clarified in section 3(d) but has been clarified by Supreme Court in Novartis case that this 'efficacy' needs to be shown by giving necessary comparative analysis and details based on relevant scientific data. The Patents (Amendment) Act, 2005 defined the term" new invention" as" any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art."The definition of" new" has been a controversial topic that has repeatedly been discussed about and a clear picture of" what is new?" has not been presented in the legal texts. In the Novartis case of Gleevec drug [1] also, the interpretation of" efficacy" has been done by the judiciary, which means that it is not clear from the provisions laid by the patents act. The provisions of newness have been discussed further in this study.

1.6. Previous studies

There have been a range of studies and research conducted in this field which have discussed about the new IPR regime in India and other developing countries. Earlier studies in Intellectual Property Rights have shown mixed impacts of patent laws. In [2] has suggested that patent laws across the world tend to magnify variation in the direction of innovation in developed and developing nations. He also said that there is only a modest effect of stronger patent norms on innovation and developmental activities. On the other hand, in many other studies like, [3] suggested that a stronger patent regime do have positive effects on innovation and R&D activities. In [4] their study focused on the need for realization of obligations to ensure access to medicines at affordable prices in the new patent regime. This shall/should remain the touchstone of the Indian patent law [5] opposed to the new patent regime saying that it is going to impact the manufacturing activity in developing countries adversely. He also argued that it might increase their imports, but may not lead to an assured increase in R&D investments, FDI inflows or access to technology which was the rationale behind the developing countries in accepting the TRIPs agreement.

In [6] has advocated for affordability of generic drugs and has also suggested the policy scope available in the context of India. He has however criticized the TRIPs on account of being unsuitable to fit the interests and circumstances of all member countries. In [7] have suggested that post-TRIPs, Indian firms have been investing heavily for new pharmaceuticals and chemical discovery and for positioning them as a partner of choice among perspicacious national and multinational firms. R&D has become survival kit in the new regime. In [8] has argued for special provisions for coordination of Plant Variety Act, Biodiversity Act, 2002 and Patents act considering adequate space for farmers' rights, breeders' rights and access and benefit sharing especially in case of developing economies.

2. Methodology

This study is an exploratory one and utilizes data from various sources in order to infer the necessary information. Most of the inferences have been drawn from the data obtained from DGCIS, WIPO, CMIE, RBI etc. The regression includes using simple OLS regression model with FDI inflows as the left-hand variable and IP protection being predictor variable.

3. Results

Patterns and Trends in Innovation and Research Activity. The Pharmaceuticals and Chemical (Fertilizers) sectors have evolved over three phases which includes period prior 1970s, i.e., before Indian Patent Act, 1970, the period from 1970 to 2005 which saw a lot of amendments in the patent regime and finally the period after 2005 under the TRIPs regime. The various Pharmaceuticals and Chemical firms have changed drastically, and the details about these changes have been discussed further. Exports and Imports in Pharmaceuticals Sector. From 1990 to 2008, there has been a gradual rise in imports and exports of pharmaceutical products in India.

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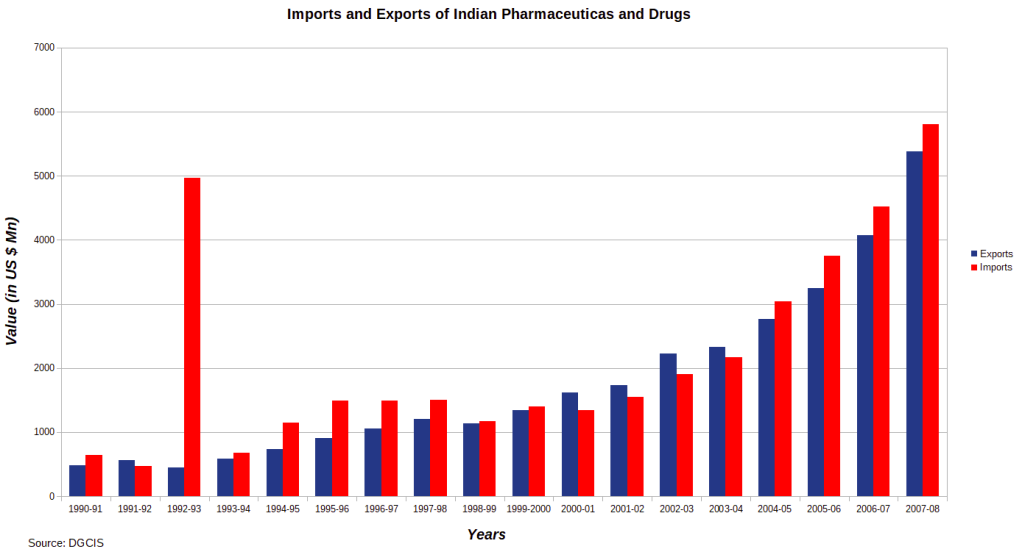
Figure 1. Patterns of exports and imports of pharmaceuticals and drugs

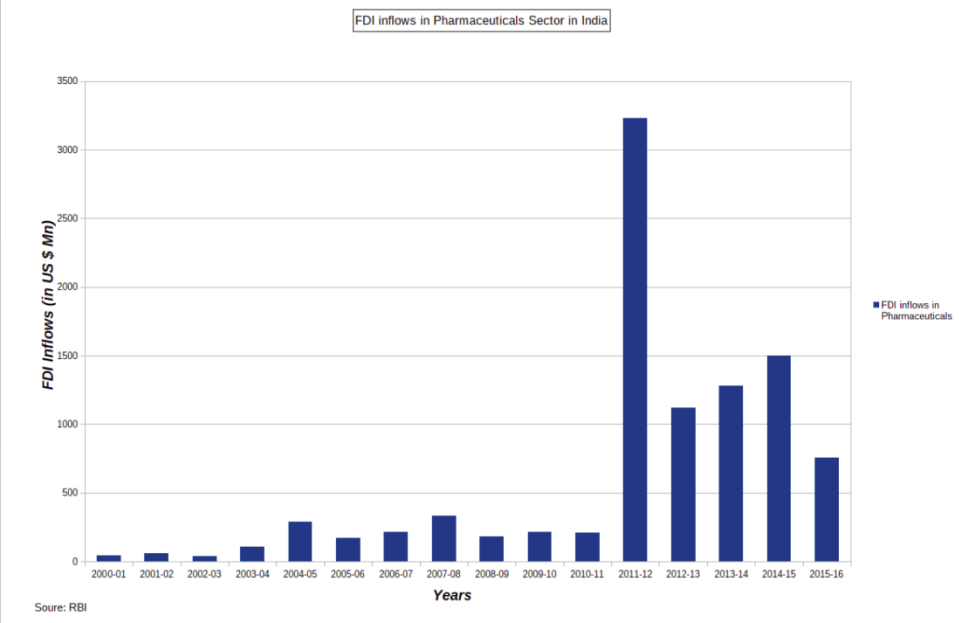


The most distinguished feature of this trend has been the period from 2000-01 to 2003-04 where Indian firms have produced at a significant pace and have been able to achieve positive trade balance. However, this trend has ceased to exist after 2005. This can be explained by reduced exports of "generic" drugs that Indian firms were efficiently producing in the pre-TRIPs era. It should also be noticed that Pharmaceuticals and Drugs share in total exports have also reduced after 2005 which is the period after implementation of TRIPs regime which means, there has been a shock to Indian Pharmaceutical industries. A similar trend can be seen in the agro-chemical sector as shown in Figure 1.

1. Trends of FDI inflows in Indian pharmaceutical sector

The FDI inflows in Indian Pharmaceuticals have gradually increased and are clear. The period from 2005 till 2008 sees an increase in inflows which suggests that there exists some relation between FDI inflows and strong intellectual property protection regime.

Figure 2. FDI in Indian Pharmaceutical Sector



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However, it can be noticed that FDI inflows have seen a decline after 2007-08 which can be due to the Global Financial Crisis, 2007-08 as it has been suggested by many researchers that Global Financial Crisis led to decline in world trade and hence the FDI inflows as well as shown in Figure 2.

2. Empirical section

2.1. Ginarte-Park Index and PIPP Index

In [9] suggested that the adoption of stronger patent-related laws and the provisional provided for the same vary greatly with the level of development of a country. It provides an IP index for a total of 122 countries till 2005. The parameters of this index include five categories which are: (1) extent of coverage, (2) membership in international patent agreements, (3) provisions for loss of protection, (4) enforcement mechanisms, and (5) duration of protection. A score from 0-1 is awarded for each, and a composite score for all the countries was thus provided. The most recent study conducted in the field of IP protection indices was the PIPP (Pharmaceutical Intellectual Property Protection) [10]. PIPP index includes three sub-indices:

(1) Pharmaceutical Patent Rent Appropriation (PPRA) Index, (2) Pharmaceutical Patent International Agreements (PPIA) Index, and (3) Pharmaceutical Patent Enforcement (PPE) Index PIPP is the product of these three sub-indices.

The following results are from the regression analysis of FDI inflows with the Ginarte-Park index and PIPP index for a dataset that includes BIMSTEC countries for year 1995, 2000 and 2005.The analysis shows that almost 22% of the variability in the data is being explained by the Ginarte-Park index, thus showing a minor correlation between Ginarte-Park index and FDI inflows. The regression analysis between PIPP index and FDI inflows is even more significant with almost 57% variability in FDI inflows data being explained by the PIPP index. That-statistic' value in this case is quite significant and thus a strong correlation can be seen. It can be thus concluded that countries tend to invest more in the countries with stronger intellectual property protection as shown in Figures 3-4.

Figure 3. FDI Inflows and its relation with Ginarte-Park IP index for BIMSTEC countries

Dependent Variable: FDI_INFLOWS__IN_US_$_MN_
Method: Least Squares
Date: 07/12/18 Time: 22:29
Sample (adjusted): 1 21
Included observations: 21 after adjustments

Variable	Coefficient	Std. Error	t-Statistic	Prob.
GINARTE_PARK_IP_IND	855.5720	221.3336	3.865532	0.0010

R-squared	0.227347	Mean dependent var	1380.304
Adjusted R-squared	0.227347	S.D. dependent var	2391.046
S.E. of regression	2101.746	Akaike info criterion	18.18537
Sum squared resid	88346727	Schwarz criterion	18.23511
Log likelihood	-189.9464	Hannan-Quinn criter.	18.19617
Durbin-Watson stat	1.253374		

Figure 4. FDI Inflows and its relation with PIPP index for BIMSTEC countries

Dependent Variable: FDI_INFLOWS__IN_US_$_MN_
Method: Least Squares
Date: 07/12/18 Time: 22:29
Sample (adjusted): 1 21
Included observations: 21 after adjustments

Variable	Coefficient	Std. Error	t-Statistic	Prob.
PIPP_IP_INDEX	2329.737	355.2974	6.557145	0.0000

R-squared	0.571429	Mean dependent var	1380.304
Adjusted R-squared	0.571429	S.D. dependent var	2391.046
S.E. of regression	1565.306	Akaike info criterion	17.59600
Sum squared resid	49003652	Schwarz criterion	17.64574
Log likelihood	-183.7580	Hannan-Quinn criter.	17.60679
Durbin-Watson stat	1.520343		

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2.2. Firms and their R&D Intensity

The post-TRIPs era, in fact even before implementation of TRIPs provisions in form of Patents (Amendment) Act, 2005, a rapid change was visible in Indian Pharmaceuticals and Agro-chemical firms has been a rapid increase in research activities after 2005. This trend is consistent with almost all the major Indian firms it can be suggested that even before implementation of TRIPs provisions, Indian firms had started with extensive research practices in order to secure patents for their discoveries as soon as India transitions into the product patent regime. As expected, the number of pharmaceuticals patents filed in India has risen significantly as result of increased investment in R&D. The data also reveals the fact that Indian pharmaceuticals and drugs patents' share in global pharmaceutical patents have risen over 1% after 2005, which were even less than 0.15% in 1990s as shown in Figure 5.

Figure 5. R&D expenditure of Indian pharmaceutical firms as a %age of their sales

YEAR	Dr. Reddy's	Sun Pharma	Glenmark	Ranbaxy	Wockhardt	Torrent Pharma	Cadila
1996	2	4	N/A	4.6	N/A	2.7	N/A
1997	2.5	3.9	N/A	4.5	N/A	2.9	N/A
1998	3.1	4	0.3	4.3	8.5	8.3	1
1999	2.2	2.7	3.6	2.9	4.3	9.6	3.5
2000	2.7	3.9	3.6	3.7	7.2	0	4.5
2001	4.2	4	12	3.3	6.2	5.3	7.9
2002	5.9	4.5	4.6	5.6	6.2	5.2	7.1
2003	9.6	7.7	9.1	6.5	7.9	7.4	3.7
2004	12.4	11.4	9.7	9.3	7.9	7.8	7.5

Source: CMIE, Prowess Database

2.3. Way forward in post-TRIPs regime

Thus, it can be concluded that the TRIPs agreement has changed the Indian Pharmaceuticals and the agro-chemical sector drastically. Thus, it can be concluded that the TRIPs agreement has changed the Indian Pharmaceuticals and also the agro-chemical sector drastically. The Indian agriculture needs a special type of protection (sui generis) that needs to be appropriately legislated.

The Protection of Plant Varieties (PPV) and Farmer's Right (FR) legislated in 2001 had an almost negligible impact on agriculture which indicates a need to revisit, review and amend the provisions of the same. The Access and Benefit Sharing (ABS) provisions under CBD, 2002 also need to be enforced.The primary aim of this paper was to provide alternative models for developing nations and least developed nations that can be adopted in the current patent regime under TRIPs agreement keeping in mind, the access to medicines (affordability) and also the food security.

2.4. Alternative models

1. Minimum patenting

The model of minimum patenting can be considered exclusively for pharmaceuticals and drugs. Under Article 27, WTO provides for product and process patents in all fields of technology considering the fact that excessive patenting are not awarded by the contracting parties. The excessive patents are harmful for all the nations since they put a road-block in the technological advancement, and would lead to non-affordability and reduced access to medicines. This is contrary to the sense that the patents are granted (refer to the introduction).

2. Donating drugs

This model can be really helpful especially to the LDCs in order to provide pharmaceuticals and a drug at an affordable rate since the expenses on medicines in these nations as discussed is an "out-of-the-pocket affair". This model includes donation of drugs to LDCs or DGs by the developed nations. However, the donating firms need to be incentivized for the same in the form of some tax benefits or other aids by the government in the developed countries.

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3. Differential pricing

The most viable and rational model that can be adopted in the global scenario is the differential pricing model which refers to the selling of pharmaceuticals and drugs at different prices in different economies based on the real per-capita incomes in the countries. In this way the firms can extract maximum profits from rich countries and can provide the medicines at a cheaper price in the least developed and the developing nations. In this case; however the problem of arbitrary/illegal movement of drugs from poor countries to the rich countries needs to be taken care of. Also, the consumers in the rich countries can stand against the political organization of the country.

4. Conclusion

This refers to the concept of differentiating patenting in rich and poor countries. Access to the life-saving drugs especially can be ensured through this model. Drugs for global diseases such as cancer, AIDS can be patented in the rich countries only so that there is a continuous inflow of the" generics" of these medicines in the poor countries. This would lead to a monopolistic market capture in the developed countries from where the firms can derive their investments on research and developmental activities. The aforementioned models offer a range of problems in implementation but are quite suitable in the present global scenario where the access to medicines and food is a major concern especially the sub-African countries.

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