

Navigating TRIPS: Analyzing the evolution and impact of Patent Law Amendments on India's Pharmaceutical Sector

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Abstract- This paper investigates the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on the Indian pharmaceutical sector. It examines the relevance of the Indian pharmaceutical sector for the economy in terms of contribution to gross domestic product (GDP) and international competitiveness. The pharma sector contributes significantly in terms of these measures. The driver of growth for the sector has been the generic drugs category, which was able to flourish under the process patent regime of the Patent Act, 1970. This is the reason that the adoption of TRIPS, and the subsequent changes in Patent Laws raised serious concerns amongst the policymakers and economists about the future of the domestic pharma industry. However, the pharma sector continues to thrive and shows positive trends in terms of industry domination, outward orientation and competitiveness.

Index Terms- TRIPS, pharmaceutical sector, patent law.

I. INTRODUCTION

The Indian pharmaceutical industry, powered by the generic drug production, cost effectiveness and innovation is a key player in providing affordable healthcare for millions across the globe. India today is known as the “pharmacy of the world”- contributing to 60% of the global vaccine production and 20% of the global supply of generic drugs. The contribution of the pharma sector to the Indian economy is also significant. It contributed 1.32% of the Gross Value Added (2011-12 constant prices) of the Indian Economy in 2020-21[1]. It is also one of the largest job creating sectors in the Indian economy.

The growth of the pharma sector in India had been led by the generic drug industry. The Patent Act, 1970 provided process patents to the pharmaceutical products. This meant that the other firms could not use the same patented process to produce a particular drug. However, if they use an alternative method to produce the drug, it was allowed. Under this regime, the pharma sector flourished by producing generic versions of the patented drugs and providing them at a reasonable price to the consumers.

However, once India became a signatory to the Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO), India had to amend its patent laws. Significantly, in the Patent (Amendment) Act, 2005, India had to shift from a system of process patent to product patent. This ensured that the patented drug could no longer be produced, even if through an alternative process. It was feared that such a change in the patent law would have severe consequences for the generic drug industry, availability of drugs in India, prices of drugs and public health.

In light of these concerns, this paper tries to answer the following research questions:

Research Question 1: What is the relevance of the pharmaceutical industry to the Indian economy in current times?

Research Question 2: What changes has India's TRIPS commitments brought to the domestic Patent Laws?

Research Question 3: How has the Indian pharmaceutical sector responded to the change in patent laws?

Research Question 4: What has been the performance of the Indian pharmaceutical industry in the post- TRIPS phase?

Research Significance

This study is significant due to the following reasons:

1. Understanding the economic impact of patent law changes will help explore the relationship between intellectual property right (IPR) laws and research and development, foreign direct investment, and overall economic growth.
2. For policymakers, it will be helpful to understand the implications of Patent Law changes to formulate future policies and strategies for the pharmaceutical sector.

The rest of the paper is structured as follows. Section II discusses the current importance of the Indian Pharmaceutical Industry. Section III analyzes the changes that India had to make to its Patent Laws to remain in conformity with its TRIPS commitments. Section IV discusses the various indicators from the performance of the pharmaceutical sector reflecting that India has responded positively to the patent law changes. Section V discusses the challenges that continue to face the pharma industry. Section VI concludes.

II. CURRENT IMPORTANCE OF THE INDIAN PHARMACEUTICAL INDUSTRY

The growth of India's pharmaceutical sector showcases the nation's thriving scientific knowledge and entrepreneurial spirit. This section provides a brief overview of the pharmaceutical industry in India, exploring its contribution to the country's GDP and employment, its export contribution, global standing etc.

2.1 Contribution to the Indian economy

The pharmaceutical sector contributed to around 1.32% of the Gross Value Added (at 2011-12 constant prices) of the Indian Economy in 2020-21[1]. The total annual turnover of the pharmaceutical industry was Rs. 3,44,125 crores in 2021-22. This makes it an important engine of economic growth- through forward and backward linkages, by attracting Foreign Direct Investment (FDI), and by generating employment. Table 1 summarizes the turnover of the sector along with the growth rates for the years 2017-18 to 2021-22.

Table 1: Turnover and growth rate of the Indian Pharmaceutical Sector

Financial Year	Turnover (Rs. In crore)	Growth Rate(%)
2017-18	2,26,423	3.03
2018-19	2,58,534	14.18
2019-20	2,89,998	12.17
2020-21	3,28,054	13.12
2021-22	3,44,125	4.89

Source: Annual Report 2022-23, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

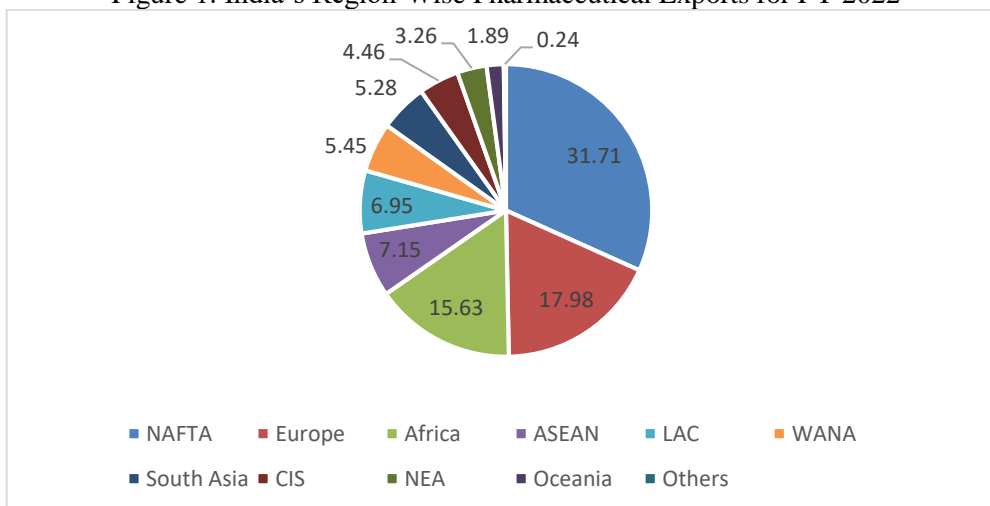
The turnover has seen a constant increase in the period under study. For three out of five years under study, the growth rate of the pharma sector was in double digits.

2.2 International competitiveness

India is a world leader in exports of pharmaceutical products. It accounts for 60% of global vaccine production, contributing 40 to 70% of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette–Guérin (BCG) vaccines, and 90 percent of the WHO demand for the measles vaccine.[2]

India is also the largest supplier of generic medicines in the world- it accounts for 20% of the global supply of generic pharmaceutical products. India provides essential medicines to more than 200 countries in the world. India's provision of affordable HIV treatment is one of the greatest success stories in the field of medicine. India plays a key role in ensuring quality and affordable healthcare solutions for millions across the globe, especially for those in developing countries. Figure 1 depicts region-wise exports of pharmaceutical exports from India for the financial year 2022.

Figure 1: India's Region-Wise Pharmaceutical Exports for FY 2022



Source: Pharmexil, Annual Report FY 2022

More than 30% of India's pharmaceutical exports are directed towards the North American Free Trade Agreement (NAFTA) countries- comprising the United States of America (U.S.A), Canada and Mexico. The second highest export destination is Europe. More than 15% of the exports also reaches Africa.

Table 2 also shows the category of pharmaceutical products exported and imported by India. The largest proportion of pharmaceutical exports comprises of drug formulations and biologicals. The second highest export category is that of bulk drugs and drug intermediaries. This is followed by the export of AYUSH and herbal products, and lastly the export of surgical items. In terms of imports, the largest category is that of bulk drugs and drug intermediaries, followed by drug formulations and biologicals.

Table 2: Category wise India's pharmaceutical export and imports for FY 2022

Category	Exports (\$ mln)	Imports (\$ mln)
Ayush and Herbal Products	612.83	111.67
Bulk drugs and drug intermediates	4,437.64	4718.37
Drug formulations and biologicals	19,015.31	3601.64
Surgicals	553.00	1011.29
Total	24,618.78	9442.97

Source: Pharmexil, Annual Report FY 2022

Thus, the Indian pharmaceutical sector plays a vital role in terms of its contribution to GDP as well as in providing affordable and quality healthcare to people across the globe, as is evident from its high levels of exports.

III. LEGAL RESPONSE TO TRIPS: AMENDMENT TO THE PATENT LAW

The TRIPS agreement lays down the minimum standards for the protection of the intellectual property rights by the member countries of the WTO. Primarily, the IPR includes patents, copyrights, trademarks, geographical indicators, industrial designs, layout designs for integrated circuits and undisclosed information or trade secrets. The TRIPS is considered a landmark agreement because it helped establish a universal framework for protection of intellectual property rights in the context of international trade, with the aim to balance the interest of the innovator as well as the public. India, along with other members of the WTO adopted TRIPS officially on 1st January, 1995.

Before the introduction of TRIPS in India, i.e. before 1995, the patent system of India was based on the Patent Law, 1970 which granted process patents, and not product patents. This meant that the drug itself was not patented, and could be produced through a different process by the manufacturers. This allowed generic versions of the patented drug to be produced and sold at affordable prices, leading to a rise of the generic drug industry of India. India was able to meet the needs of its as well as that of other developing countries by providing essential and affordable drugs. India's pharmaceutical sector really boomed in this period.

With the adoption of the TRIPS, things had to change. India adopted TRIPS in 1995. Being a developing country, India was granted a transition period of 10 years i.e. till 2005 to bring its domestic patent laws in conformity with the requirements of the TRIPS. It required India to transition from a system of process patent to product patent. This meant

that the manufacture of the patented drug itself was not allowed, even if through a different process. It was believed that this would provide a big blow to the generic drug industry of India, and the availability and prices of essential medicines.

The Indian patent law was amended twice to incorporate the required changes.

The Patents (Amendment) Act, 1999: This was the first step towards complying with the TRIPS requirements. The Patent Amendment Act, 1999 introduced the “mailbox applications” where the filing date of the pharmaceutical inventions were preserved till the implementation of the product patents.

The Patents (Amendment) Act, 2005: India fully complied with the requirements of the TRIPS by the adoption of the Patents (Amendment) Act of 2005. Product patents were granted for all inventions with effect from 1st January, 2005.

It was understood that this could have a devastating impact on the pharmaceutical industry of India which was thriving on the production of generic drugs. The Government also adopted certain flexibilities and allowed some provisions in the law to protect the pharmaceutical sector, without violating its TRIPS commitments. They are as follows:

(a) Section 3(d): This section allows for the patenting of new forms, new uses, or new processes of known substances, as long as they involve an inventive step and differ significantly with respect to its efficacy. This prevented the attempts of “evergreening” by the pharmaceutical companies.

(b) Compulsory Licensing: The Act retained the ability to grant compulsory licenses under specific circumstances, such as public health emergencies, non-working of the patent, or excessive pricing. This safeguard aimed to ensure public access to essential medicines at affordable prices when market forces failed to do so.

Thus, India’s patent law had to be amended significantly to adapt to the TRIPS requirements. This did bring India closer to the international norms with respect to intellectual property rights. To protect the general interest of public health, India also adopted a stricter stance with respect to the “evergreening” of patents as well as retained flexibility to grant compulsory licensing. These two steps are believed to have significantly protected the interest of India to ensure access to essential medicines for its people.

IV. INDICATORS OF POSITIVE ADJUSTMENT TO THE PATENT LAW

This section looks at some of the key indicators of performance of the Indian pharmaceutical industry in the post-TRIPS era to analyze how the sector has responded to the changes in Patent Law.

a) *Global prominence*

India had maintained its competitiveness in the global market of generic drug manufacturing. Table 3 shows that seven out of the top twenty companies globally in the manufacture of generic drugs were of Indian origin in 2021-22.

Table 3: Indian Pharmaceutical companies in top global generic manufacturers:

S.No.	Global Rank	Company	Turnover (\$ million)
1	6	Sun Pharma	4474
2	7	Aurobindo Pharma	3345
3	11	Cipla	2587
4	12	Dr. Reddy’s Laboratories	2561
5	13	Intas	2237
6	15	Lupin	2047
7	17	Zyduscadila	2044

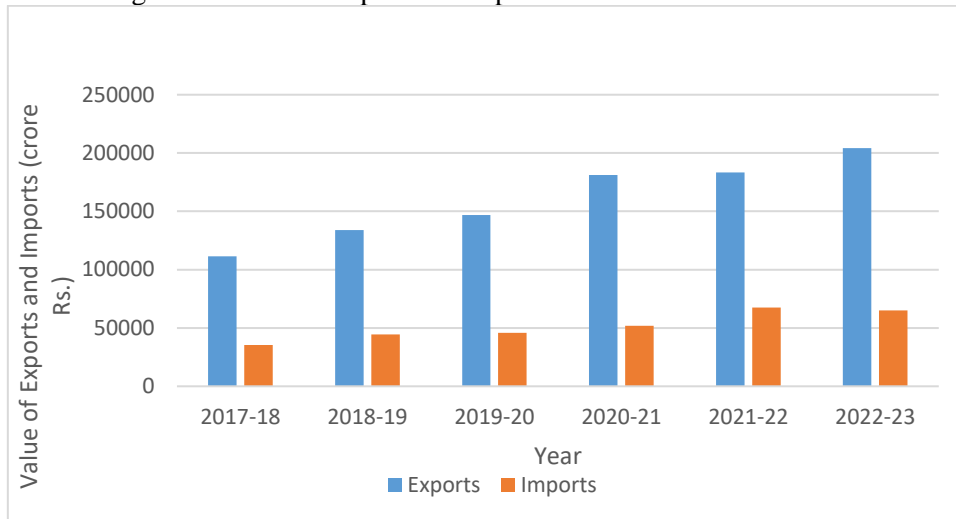
Source: Pharmexcil, 18th Annual Report 2021-22

The companies to feature in the global list includes Sun Pharma (6th rank), Aurobindo Pharma (7th rank), Cipla (11th rank), Dr. Reddy’s Laboratories (12th rank), Intas (13th rank), Lupin (15th rank) and Zyduscadila (17th rank). Thus, Indian companies have retained their international competitiveness in the field of generic drug manufacturing and are world leaders today.

b) *Exports and Imports*

The levels of exports and imports of pharmaceutical products is another indicator of the integration of the Indian pharma industry with the rest of the world. Figure 2 depicts the value of exports and imports from/ to India in the last six years.

Figure 2: Value of Export and Import of Pharmaceutical Products



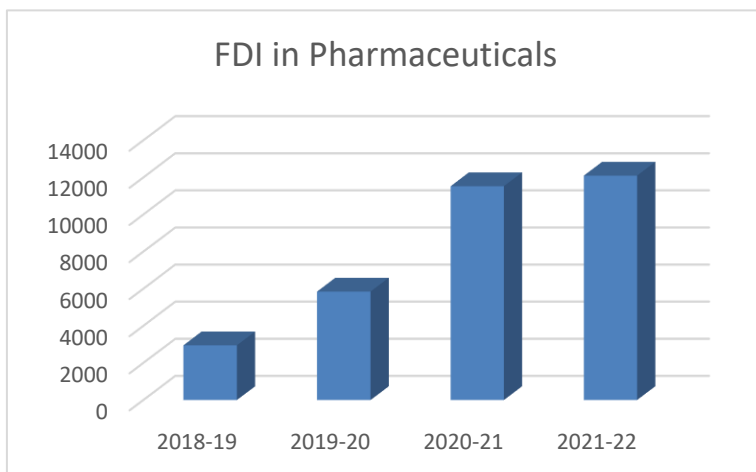
Source: DGCIS

The value of exports from India has shown a consistent increase over the last six years. This is another testament to the increasing competitiveness of Indian pharma products and the increase in demand by the foreign countries.

c) Foreign Direct Investment

The pharmaceutical sector of India has emerged as one of the top ten sectors attracting the highest amount of foreign direct investment in the country. The pharma sector contributes to around 3.71% of the total FDI inflows in the country.

Figure 3 depicts the FDI in the pharmaceutical sector in the last four years (including MedTech activities). Table 4 shows the FDI inflows in the drugs and pharmaceuticals.



Financial Year	FDI inflows (drugs and pharmaceuticals)
2018-19	1,842
2019-20	3,650
2020-21	11,015
2021-22	10,552
2022-23	16,654

Figure 3: FDI in Indian Pharmaceutical sector

Table 4: FDI inflows

Source: DGCIS

Source: <https://fdi.pharmaceuticals.gov.in/>

We can witness an increasing trend in the FDI inflow in the pharmaceutical sector. The FDI has gone up from Rs. 1,842 crores in 2018-19 to Rs. 16,654 crores in 2022-23. Rising FDI is a reflection of investor confidence in the sector and future growth prospects.

Responding to the influx of FDI, the government also has put in place a welcoming FDI policy to promote investment in the sector. Currently, 100% foreign investment is permitted for medical devices under the “automatic route”. For the “greenfield projects” in pharmaceutical sector, up to 100% FDI is permitted through the “automatic route”. For the “brownfield projects” up to 74% FDI is allowed under the automatic route, with government approval requirements for

exceeding this threshold. This inflow of foreign capital has played an important role in increasing the levels of innovation and technical advancement of the domestic firms.

Thus, in terms of its international competitiveness, value of exports as well as the inflow of FDI in to the Indian pharmaceutical industry, the sector has done well in the post-TRIPS era.

V. CONCLUSION

In conclusion, the findings point towards the resilience of the Indian Pharmaceutical industry after implementing the TRIPS agreement. The pharmaceutical sector has emerged as a significant contributor to India's gross domestic product (GDP) and a global player. Some key indicators of this identifies in this paper includes- rising exports, increasing trends of FDI and global prominence of Indian companies. These put to rest the initial fears of harmful effects on the domestic pharmaceutical industry.

However, it is important to acknowledge that some challenges remain to be addressed in the post TRIPS era. The research and development(R&D) expenditure of Indian firms is still lower than that of many developed countries. Additionally, while the bigger firms have done well in the post-TRIPS era, the smaller firms have not been able to perform as well. Most importantly, the concerns about affordability of patented drugs are well founded for certain segments of the population. There is a delicate balance between innovation and public health that has to be maintained, and active steps by the government are required by the government to ensure this.

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