The Effect of Trips on Indian Pharmaceutical Industry

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Abstract **- The Treaty on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was enacted with the goal of unifying intellectual property rights norms and putting developing countries on an equal footing with rich countries. A few factors, such as scientific progress, fresh breakthroughs in biotechnology, the rising inclusion of the private sector in cost-intensive research and development in the knowledge-based pharmaceutical sector, and the overall power demonstrated by developing countries in adjusting the results of scientific innovations to the local environment, have all contributed to this trend. have pushed developed countries to seek tighter protection for their technologies across the board (1). Because of the quality and cost-effectiveness of its products, the Indian medicines industry is now well-known around the world. It is currently one of the fastest-growing industries in the world, contributing 2.4 percent in terms of value and 10% in terms of volume. India alone is responsible for 20% of worldwide generics exports. The Indian pharmaceutical sector exported USD24.44 billion in 2021 and is predicted to hit USD65 billion by 2024.**

Index Terms **- TRIPS, Patent, WTO, Pharmaceutical Industry, Issues and Opportunities.**

INTRODUCTION

In the pharmaceutical and biotechnology industries, intellectual property rights (IPR) play a critical role. Within pharmaceutical industry, the health sector clearly determines the market price of medications, although during the recession, most firm owners invested their money in R&D and increased their IPR cells. It also describes the patent, the recovery of a patent term, and the change of laws that have recently been implemented by other countries. Additionally, it addresses the ever-greening of patents as well as the medicine cost aspect. The relationship between the General Agreement on Tariffs and Trade (GATT) and intellectual property rights (IPR) is explored. In the domain of biotechnology, IPR refers to the profit generated by biotechnology firms through intellectual property protection, as well as the implications of new trends in the field. Through IPR, the biotechnology patenting process is a contentious issue (2). A solution developed, and it also assisted in the survival of the biotechnology businesses in India and around the world.

The Indian Patent Act was amended in 2005 to eliminate the process patent regime and replace it with a product patent system. The generic industries that were successful in patents and reverse engineering were not allowed after the amendment. Because the pharmaceutical industry spends billions on research and development, the price of the product reflects this (3).

While affordable medicine is an essential component of the right to health, rising prices have a negative impact on accessibility in developing nations like India, where a large portion of the population lives in poverty. As a result, India has introduced TRIP flexibilities and effective use of compulsory licencing to enable maximum access to health care (4). The Supreme Court's recent judgements on this issue show that the Indian judiciary is attempting to strike a balance between public necessity and scientific progress.

According to the TRIPS agreement's minimum standards, patents will be granted for any inventions, whether products or processes, in all fields of technology that are new, involve an inventive step, and are capable of industrial application, regardless of where the invention was made or whether the products were made locally or imported. As a result, patents must now be issued in all fields, including pharmaceuticals, with a twenty-year effective duration of protection beginning on the day of filing the application. By 2005, most developing countries will have implemented the TRIPS agreement, resulting in a strengthened patent regime or product patents that will be consistently applied to pharmaceutical discoveries among WTO member countries (5).

The following are the implications of TRIPS for the pharmaceutical industry: patents will be allowed for

both production processes for all inventions across all fields of science and technology; the patent term will be twenty years from the date of application (compared to seven years under the 1970 Act); the patent term will be relevant to all member countries and thus eliminates all differences in the protection terms prevailed in different countries(6); patents will be granted irrespective of whether the invention is for a product or a process. A person other than the patent holder can sell the patented item's production or other rights (7). In a patent infringement lawsuit, the accused, not the patent holder, bears the burden of proof (to show that a procedure other than the one employed in the patented product was actually utilised in the disputed product) (in the 1970 Act, the responsibility is with the patent holder). This is the basic framework within which India's pharmaceutical industry would operate under the WTO (8).

India's views on stronger patents for the pharmaceutical business are disputed, with some coming from the country's historical experience using product patents and others coming from countries that have only recently adopted product patents. Such evidences imply that a country's level of IPR effects a number of social and economic issues, ranging between common people's good healthcare to domestic industry's functioning, investment in R&D, and technology, among others. India, Argentina, and Brazil, in particular, were the most strident opponents of the TRIPS agreement, and India was more vocal in expressing her opinions on difficulties highlighted by industrialised countries (9). All three nations have already adopted the TRIPS agreement as a result of pressure from various places, and India is now looking for flexibility within the TRIPS structure that will benefit its people, industry, and economy. By removing the hurdles that exist in the form of variations in intellectual property norms, the worldwide TRIPS regime is projected to result in free flow of trade, investment, and technical know-how across member nations. There seems to be a wealth of research available that examines the potential consequences of a global IPR policy (10).

The Significance of TRIPS On the Pharmaceutical Industry in India and The Amendment of Indian Patent Law

The Indian Patent Law was changed three times between 1995 and 2005 to conform with TRIPS (11). The Patents (Amendment) Act of 1999 created the mailbox procedure, which allowed pharmaceutical inventions to be accepted and stored in a mailbox until they were evaluated in 2005, as per Article 70.9 of the TRIPS Agreement.

In 2002, the Second Amendment established a 20-year patent term. The burden of proof for method patent infringement was flipped in this case, as were the conditions for forced licensing (12).

The Patents (Amendment) Act 2005, the third and most recent Amendment, provided pharma full patent protection.

There was no product patent for pharmaceutical items prior to the 2005 Amendment. This Amendment replaced process patents with product patents, allowing for a broader system of compulsory licencing (13). It also included provisions on 'patentable subject matter' and 'exhaustion of patent rights,' as well as a mechanism for both 'pre-grant' and 'post-grant' opposition to patent applications, as well as the creation of an 'inventive step' for patentability under the patent regime.'

Awarding product patents to pharmaceutical innovation has had a negative impact on developing countries like India, limiting the supply of affordable treatments and indirectly removing generic competition, which had previously thrived by delivering patented medicines at a low cost.

Prior to 1970, the pharmaceutical industries in India were controlled by foreign corporations. The Indian pharmaceutical industry, on the other hand, had tremendous expansion between 1970 and 2005. The Patent Act of 1970 was responsible for this development (14).

The above Act established the process patent and reduced the duration of pharmaceutical patents. Due to the lack of a product patent, medications might be produced at their original cost. It also enabled generic pharmaceutical companies to reduce drug production costs, limiting the growth of multinational pharmaceutical corporations in India. As a result, India was self-sufficient in bulk medicine manufacture by 1990 (15).

The product patent regime was authorised in India after the 2005 Amendment. The Indian generic industries, on the other hand, were not allowed to ‘reverse engineer' the copyrighted pharmaceuticals, resulting in higher drug prices.

INDIAN PHARMCEUTICAL INDUSTRY-OPPORTUNITIES AND CHALLENGES

The Indian market, with a population of over a billion people, remains virtually untapped. In truth, just about 30% of Indians have access to modern treatment. To put things in perspective, India's per capita health-care expenditure is US$ 93, while Brazil's is US$ 453 and Malaysia's is US$ 189. The country's growing middle class has resulted in rapidly changing lifestyles in both urban and rural areas. This creates a massive market for lifestyle medications, which now have a small share of the Indian market. India's pharmaceutical manufacturers are among the world's most cost-effective. With a labour force that can be scaled up and down, Drugs manufactured in India can be produced at a cost of 40% to 50% less than those produced elsewhere in the world. This cost can be as low as 90% in some circumstances. The Indian pharmaceutical sector is very skilled in chemistry and process reengineering. This strengthens the Indian firms' competitive position. The chemistry expertise of Indian enterprises aids in the development of cost-effective methods. In the long run, the transition to a product patent-based system is likely to change the fortunes of the sector. New novel drugs will emerge as a result of the new patent product framework (16). MNC pharma businesses will benefit more as a result of this, while domestic pharma companies will be forced to focus more on R&D. This migration could also lead to consolidation. Smaller players may be unable to cope with the difficult environment and succumb to giants. Between 2005 and 2009, a large number of pharmaceuticals in Europe and the United States went off patent, creating a huge opportunity for Indian companies to seize this market. Because generic medications are commodities by nature, Indian producers have a competitive edge because they are the world's lowest-cost drug producers. Long-term growth drivers include the opening up of the health insurance industry and predicted increases in per capita income (17). As a result, the healthcare business, of which the pharmaceutical industry is a vital part, expands. Indian enterprises can become a worldwide outsourcing hub for pharmaceutical items because they are the lowest-cost producers with USFDA-approved factories.

Price restrictions has harmed Indian pharmaceutical industries. Over time, this regulation has harmed businesses' power to set prices. The NPPA (National Pharma Pricing Authority), which is in charge of determining various pricing factors, sets prices for various pharmaceuticals, associated with decreased profits for pharmaceutical corporations. Companies that produce at the lowest cost have an edge, whereas those who cannot provide must either quit or lose money (18). The lack of product patents in India has hampered the country's pharmaceutical industry, making it difficult for multinational pharmaceutical corporations to market new treatments and discouraging innovation and drug discovery.

Conversely, this has given Indian pharmaceutical businesses an advantage. The Indian pharmaceutical market is one of the worlds least developed. Growth, on the other hand, has been gradual. Like a response, India's largest corporations are increasingly reliant on exports for growth. To put things in perspective, India has about 16 percent of the world's population, yet its pharmaceutical business accounts for only 1% of the worldwide market. The Indian pharmaceutical business is extremely fragmented, with roughly 300 large manufacturing units and about 18,000 minor units distributed across the country due to low entry barriers. As either a result, the Indian pharmaceutical sector is becoming highly competitive (19).

Price competition exists in the business, reducing the industry's value-added growth. To put things in perspective, the industry increased by 10.4 percent in 2003, but the rise in value terms was only 8.2 percent owing to price competition (prices actually declined by 2.2 percent). There are certain reservations about the existing structure of the patent regime. It's probable that the new government will amend some of the terms of the patent statute drafted by the previous administration. Other low-cost countries, such as China and Israel, pose a threat. On the other hand, India outperforms China in terms of quality (20). As a result, differentiation in contract manufacturing may dwindle. The uncertainty surrounding VAT introduction is a short-term threat to the pharmaceutical business. Though this is expected to have a negative impact in the short term, the long-term implications for the industry are favourable.

Pre-TRIPS Period in the Indian Pharmaceutical Industry

Over the previous four decades, India's pharmaceutical industry has grown steadily, and it has

become one of the world's leading generics players. India has grown into a major drug-producing nation. In the late 1980s, the Indian pharmaceutical sector, which had limited technological capacity to produce medications locally in the 1950s, reached manufacturing self-sufficiency and became one of the world's major drug exporters. The weak patent regime of the Patent Act of 1970 and the Drug Policy of 1978 fuelled the industry's growth. Following India's independence, the Indian government established two committees, the Tek Chand Patents Enquiry Committee (1948–1950) and the Ayyangar Committee (1959), to improve the availability and cost of vital pharmaceuticals in the country. These committees proposed modifying the Designs and Patents Act of 1911, which acknowledged pharmaceutical product patents (21). The Patent Act of 1970 did, in fact, replace this act (Ramannna, 2002, pp. 2065–2066). Only process patents were authorised by the Patent Act of 1970, which lowered the patent length from 16 to 7 years. Three years after the patent was obtained, automatic licences of right could be given. The statute gave Indian pharmaceutical businesses the ability to develop alternative techniques for pharmaceuticals that were not copyrighted in the country. From the 1970s to the 1980s, Indian businesses began to do their own R&D. The Patent Act of 1970, which offered a limited intellectual property protection environment, was a turning point in India's growth of domestic pharmaceutical R&D. Reverse engineering and the creation of alternative procedures for products patented in other countries were encouraged by the act (22). India's first comprehensive drug policy was enacted in 1978. The policy's basic concept remained largely unchanged until the 1990s. The legislation's primary goal was to establish drug production self-sufficiency. The strategy highlighted the importance of research and development (R&D) and technology, and provided R&D-promotion measures to help the Indian pharmaceutical industry improve its technological capabilities. To be compatible with the policy's core goal of promoting the manufacture of bulk pharmaceuticals and intermediates, certain procedures for guiding and controlling foreign enterprises with a 75 percent share. Advances in domestic R&D were aided by the Patent Act of 1970 and the Drug Policy of 1978.

The act of 1970s and the 1990s, India's ability to create generic pharmaceuticals was acquired, improved similar industrial policy initiatives, including the Foreign Exchange Regulation Act of 1973 (FERA) and also the Drug Price Control Order of 1970 (DPCO 1970), which were meant to discourage foreign investment, also played a significant impact in the industry's development (23).

Since the early 1980s, the Indian pharmaceutical industry, which relied on reverse engineering and process innovation to establish technological self-sufficiency, has been boosting its export orientation amid the current wave of economic liberalisation. The sector has demonstrated good global innovation index potential and is going to rise its global presence. Since 1987, the pharmaceutical trade surplus has been rising. GMP, or good manufacturing practice, is a mechanism for ensuring that products are regularly manufactured and managed according to quality standards, which has improved the marketability of Indian medications. The Drug Policy of 1986 was the catalyst for India's decision to implement GMP (24). Schedule M of the Drugs Cosmetics Act, 1940 and Rules, 1945 established GMP, which went into effect in 1987. The implementation of GMP aided in increasing consumer confidence in Indian products on the international market.

TRIPS Agreement's Impact on the Indian Pharmaceutical Industry

The Indian pharmaceutical sector has been confronted with a number of new issues as a result of the institutional elements that had aided the industry's expansion were altered by a 1970 modification to the Patent Act that introduced product patents. The legislation was expected to have a detrimental impact on India and stifle the growth of the country's pharmaceutical industry because it would no longer be allowed to reverse-engineer or export medications with product patents in place. The Indian pharmaceutical sector is pursuing a new business strategy in light of the TRIPS Agreement and imminent revisions to the Patent Act of 1970 (25). Pharmaceutical businesses have been participating in the pharmaceutical GVC through worldwide collaborative relationships with global pharmaceutical companies in the post-TRIPS period, while boosting their R&D spending.

Indian Pharmaceutical Companies' R&D orientation has shifted

R&D in the Indian pharmaceutical business was mostly focused on the development of novel drug production processes until the mid-1990s. This was changed by the TRIPS Agreement. The TRIPS Agreement has transformed the Indian pharmaceutical industry's R&D strategy as well as boosted R&D expenditures.

Pharmaceutical businesses in India are expanding their R&D spending in order to develop new products. The pharmaceutical industry is heavily invested in research and development. Under the TRIPS Agreement's pro-patent framework, the pharmaceutical industry's long-term growth is dependent on constant R&D for the discovery of new medications and technology (26).

In order to compete in the global pharmaceutical industry, Indian companies have expanded their R&D spending. R&D is becoming more important to businesses. Novel drug delivery systems (NDDS), new drug development research (NDDR), and biopharmaceutical R&D are the emerging R&D priorities.

Drug Delivery Systems that is unique

Indian pharmaceutical companies are not only licensing their NDDS technology to global pharmaceutical companies, but they are also using the licensing agreements to introduce new technology from global pharmaceutical businesses into the development of NDDS. Since 1987, the pharmaceutical trade surplus has been rising. GMP stands for good manufacturing practice.

Research on New Drug Development

The adoption of pharmaceutical product patenting, according to supporters of the TRIPS Agreement, will boost R&D for new medicine development. In the mid-1990s, Indian pharmaceutical companies began investing in NDDR R&D. Several major Indian pharmaceutical corporations are now active in NCE research and development and have established their own NDDR research centres (27). Some Indian firms, such as Zydus Cadila and Glenmark, have experienced NDDR success. These firms have a robust pipeline of new compounds in various preclinical and clinical phases.

Despite the fact that Indian pharmaceutical companies have increased their R&D spending, the majority of them cannot afford the R&D costs associated with developing and launching a product because they are small in comparison to most global pharmaceutical companies and operate at the lower end of the value chain. For all of these reasons, several Indian companies have adopted a strategy of discovering new compounds and licensing them out to giant global pharmaceutical companies at an early stage of clinical research. Collaboration with major pharmaceutical corporations is becoming more common.

Biopharmaceutical Research and Development

In the late 1990s, the Indian pharmaceutical sector began to invest in biopharmaceutical R&D. In India's biotech industry, the biopharmaceutical segment had the highest revenue share (64%) in 2016. In terms of both domestic and international sales, biopharmaceuticals are the industry's largest segment (India Brand Equity Foundation (IBEF). Vaccines, biopharmaceuticals, and diagnostics are the three key biopharmaceutical areas in India.

India was the first country to begin biosimilar research and development. Biosimilars have been available in India since the early 2000s, long before they were introduced in Europe in 2006.

Biosimilars are being developed with the goal of receiving marketing authorization in regulated Indian markets. In the post-TRIPS period, Indian pharmaceutical businesses have boosted R&D expenditures while also becoming more R&D-oriented and intensive, as indicated above (28). As their R&D experience grows, Indian pharmaceutical businesses' technological level has continuously improved. Through superior R&D technology, Indian pharmaceutical businesses are expanding their influence in the global pharmaceutical market. In the post-TRIPS era, India's pharmaceutical business is rising up the value chain.

CONCLUSION

The Indian pharmaceutical industry is ever so far one of the most diverse, knowledge-driven, and technology-intensive growth areas, with the potential to create considerable resources through rapid advancements. When TRIPS was signed, many people predicted that it would affect India's pharmaceutical industry. However, if India sought to grow its pharmaceutical business by attracting large foreign companies to invest in the country, the patent legislation became critical. It is common knowledge that it costs a lot of money to bring a new drug to

market, and the company that makes it wants to make money (29). In the case of a pharmaceutical company, intellectual property rights (IPR) play a critical part in the patent filing process. enforcing legal penalties against counterfeit medication manufacturers and developing the industry's reputation in the market for drug safety and quality. In India, it raised awareness about patents, which aided corporations in applying patents in profitable areas, and international treaties were signed, which will aid Indian companies in filing multiple applications. In the sphere of biotechnology, IPR responses played a critical role in safeguarding plant, animal, and human welfare. GMO will be a terrific protein supplement to human life in the approaching years. As little more than a result, these are legally protected, but dangerous operations such as cloning are absolutely prohibited in humans.

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