INDIA'S CURRENT SITUATION REGARDING INTELLECTUAL PROPERTY RIGHTS IN THE PHARMACEUTICAL SECTOR

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Abstract

When India's patent law was changed to align with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), it made it harder for generic pharmaceutical companies to do business. Two of the most important changes were the creation of a product patent system for medicines, which replaced the old process patent system, and the lengthening of pharmaceutical patents from 5 to 7 years to 20 years (5 years from the sealing of the patent or7 years from the date of application, whichever was lower). In the 1980s, a generic pharmaceutical company was started because of India's pre-TRIPS patent policy. This policy banned product patents in the pharmaceutical industry. How did the Indian pharmaceutical industry deal with the problems caused by the product patent regime, which aligns with TRIPS? When researchers looked into the factors affecting large industrial companies' size and operational strengths, they found no structural problems in generic businesses. They stayed at the top of the market regarding capital invested and business size. They stayed in business and made more money than the rest of India's major industries. Even though all the big generic drug companies make generic drugs, they still spend much of their sales money on research and development (R&D). They worked hard to get patents, even though they filed far more in other countries.

Keywords: India's patent law, GVC framework, TRIPS, generic drugs, R & D

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1. Introduction

The pharmaceutical industry is crucial to the survival of humanity and is expected to expand quickly in the next few years, particularly after 2020, when the impact of COVID-19 will be enormous. India's pharmaceutical industry has rapidly advanced to become a global leader in several categories of drug production, including generics and vaccines. The Food and Drug Administration (FDA) of the United States is only one of the many international drug regulatory authorities that have approved Indian pharmaceutical companies. India is becoming a significant player in the pharmaceutical industry because of the investments of several multinational businesses.[1]

India ranks sixty on the 2017 Global Innovation Index (GII) regarding how well it uses new technologies. It ranks below countries like Ireland (10), South Korea (11), and China (22). The United States came in fourth, trailing Switzerland in the GII rankings. Healthcare industry in India (Figure-1)has a formidable challenge regarding innovative healthcare management technologies.[2]The growing cost of health care and the goal of universal coverage constitute a considerable challenge to the governance and equity of the Indian health system. Information technology (IT) and innovation can deliver excellent services at a reduced cost, including the e-profiling of patients, medical claim adjudication, referral, pre-certification services, case management, digital imaging, and electronic medical records (EMRs).[3]

Technological innovation is becoming more regulated and predictable, yet the healthcare industry is trapped between cutting-edge technology's competitive advantage and unpredictable risk. In health care management, non-disruptive or disruptive innovation technologies are classified. Non-disruptive innovation is an evolutionary, slow, linear, and sustained transformation that increases current extra opportunities. In contrast, disruptive innovations result in transformational and exponential development. Technology innovation profoundly impacts current systems, generates new market components and marketplaces, and offers valuable opportunities to change adaptors. The healthcare industry is projected to experience several disruptive innovation technologies; thus, the innovations are critical now. There is a negative relationship between IT innovation and IT-enabled innovation in health care. According to McKinsey research, the American healthcare industry's productivity decreased by 0.8% per year between 1990 and 2007, while the computer and semiconductor industries' wealth climbed by 7.6% yearly**.**Breakthroughs in healthcare technology and pharmaceutical accessibility have resulted in major increases in world health. Because of pharmaceutical company patents, most patients in developing countries, which account for about 75% of the world's population, are denied access to prescription drugs. Combating epidemics such as Ebola and Zika, neglected tropical illnesses (DTNs), and a lack of antiretroviral medications (ARVs) for HIV/AIDS is conceivable. However, too little money is invested in health technology research and development. 12 According to World Health Organization data from 2016, inadequate resources have been devoted to HIV/AIDS, TB, malaria, hepatitis, and other neglected tropical illnesses.

The TRIPS Agreement of 1995, the Patents (Amendment) Act of 1970, the Patents (Amendment) Act of 1999, the Patents (Amendment) Act of 2002, and the Patents (Amendment) Act of 2005 control the legal and intellectual property elements of health and access to pharmaceuticals in India.

The post-TRIPS Agreement of 1995 and subsequent revisions stressed human rights to health and their ties to intellectual property rights. Medication availability is an important public health issue. The world's leaders try to address and settle the TRIPS Agreement of 1995 and the Doha Declaration on Public Health of 2001 by making several compromises in the name of greater public welfare. The United Nations Sustainable Development Goals (SDGs) for 2015–2030 enhance this endeavour by prioritizing the health and well-being of all people.

Figure 1: IPR In India

India's pharmaceutical sector is growing, and the government highly values its safety and efficacy. In the 1980s, India had a thriving generic pharmaceutical sector that offered drugs at the world's lowest costs. The generic sector developed greatly due to the Patents Act of 1970, which replaced the Colonial Patents and Designs Act of 1911. Two key aspects of the 1970 Patents Act were critical in recruiting more entrepreneurs to the pharmaceutical business. First, the 1911 Act's product patent system, which covered all compounds, was abolished and replaced with a process patent framework. 7,8The second revision reduced the term of pharmaceutical process patent protection from 14 years to five years from the date of award or seven years from the date of application, whichever is shorter. Patent protection lasts fourteen years in all other technological disciplines. The process patent system allows Indian firms to create new methods of producing generic versions of medications covered by intellectual property rights. The pledges made by India to implement the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 9 altered the scenario for the generic industry, which had previously been in a favourable position. Setting up the product patent regime, which made it more difficult for generic enterprises to avoid proprietary techniques, was a major concern. As a result, the survival of these enterprises was heavily reliant on Indian authorities' ability to build a patent regime that integrated the TRIPS Agreement's flexibilities. [9]Because the pharmaceutical industry is an important aspect of the nation's healthcare sector, the government is taking the required actions. As a result, improving access to medication and the human right to health in India necessitates extensive legal and intellectual property efforts. India's patent rules were linked with the TRIPS Agreement, resulting in two significant changes. The first was an expansion of patentable subject matter to include microorganisms and "essentially nonbiological processes," as well as a twenty-year extension of the patent period from the date of application. [10]Demographic trends, lifestyle-related diseases, rising middle-class income and disposable income, expanded healthcare infrastructure, aggressive market penetration, and product patent approval contribute to India's growing need for medications. The Indian pharmaceutical industry strives to be internationally competitive and sustainable. It has developed world-class manufacturing processes that have expanded Indian pharmaceutical export potential, lowered production costs, and increased research capability. [3]However, as was previously said, the sector faces several difficulties, with patents being the biggest. The capacity of a nation to get patents, which is the sole means of maintaining market share, is a key factor in the pharmaceutical industry's profitability. Such efforts can require high R&D and knowledge-building costs. From an IC perspective, this line of reasoning is crucial because the intellectual property, such as patents, may serve as "proxies" for IC capital requirements, enabling India to sell medicines at higher prices while maintaining a more stable financial structure. [6]Unfortunately, the regulations as they are now are not intended to encourage patent applications. The actions of other nations—most notably China—will undoubtedly impact how much the Indian government decides to increase patent applications. 11 In India; pharmaceutical clusters may benefit from a variety of subsidies, such as cash incentives, tax breaks, and exemptions. [12]The government's changes to the IP framework have caused the sector to expand and strive for more dominance on a national and worldwide level. Because the creative industries have the potential to be very lucrative, the policy is crucial to their development. According to Prakash et al. (2018), medicines receive the highest number of patent applications despite having a lower clinical conversion rate in India. [13] Economic models based on patents play a minor role in the development of the industry. They are primarily responsible for slow progress, a lack of a multidisciplinary approach in preclinical and clinical studies, inadequate funding, competing interests across involved sectors, and inadequate staff training. Generic medications currently dominate the Indian pharmaceutical market. Additionally difficult is the environment for product patents. Therefore, it is crucial to improve India's IPR system. [11]The pharmaceutical global value chain (GVC) has been reorganized since the TRIPS Agreement **(**Figure 2) was formed and has now expanded to growing nations like India. Thus, Indian pharmaceutical companies participated in the GVC post-TRIPS era. Participation in this activity promotes technical advancement and technology transfer. Indian pharmaceutical companies are modernizing their operations while participating in the GVC by implementing cutting-edge technology. [9]

Patent Regulation Consistent with TRIPS in India

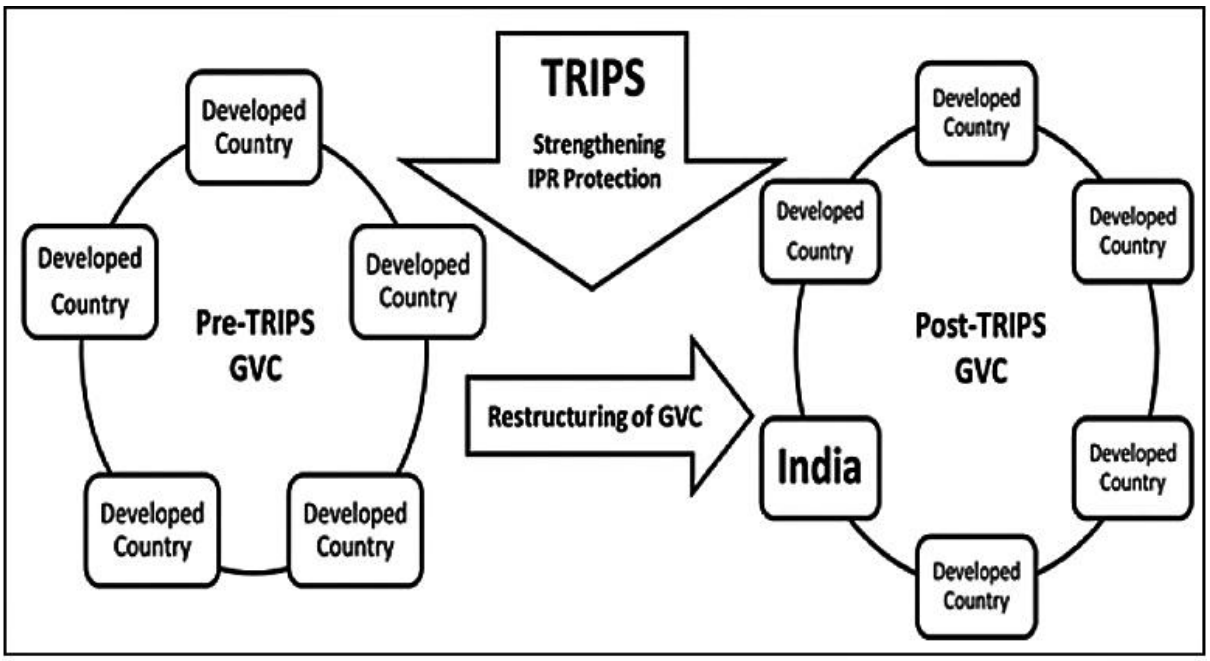
India's post-TRIPS patent law makes an effort to strike a balance between the rights of the patent holder and the requirements of the public interest by using two sets of rules. The first is focused on the parameters of patentability. The system of licensing requirements is the second.

Limiting the Grant of Patents for Simple Variations under Section 3(d)

"Merely finding a novel version of an existing chemical without increasing its recognized effectiveness

A patent is only sufficient to cover a modest addition of a new property or new application for a known substance or the simple use of a known method, machine, or equipment if such a known process produces a new product or uses at least each new reactant. The Uruguay Round

Figure 2: Changes of GVC in Post-TRIPS Period



negotiations that resulted in the TRIPS Agreement served as the foundation for Section 3(d). Participants concentrated on the problems brought up by inadequate patent protection to recover the benefits from research and development (R&D) activities. They claim that new standards and laws for intellectual property (IP) protection, extending the patent protection period, are appropriate. They felt it would effectively motivate R&D activities to enable the development of novel chemicals. Only when innovators produce unique products and processes, rather than merely small tweaks to well-known molecules, may extended patent protection be justified.The fact that Section 3(d) prohibits patent "evergreening" is another compelling reason in its favor. Many of the original businesses have made it a standard practice to make little changes to drugs that are copyrighted, apply for another "full" period of patent protection on the alterations, and keep repeating this process indefinitely (hence the name "evergreening").

System of compulsory licensing

The Indian government established the compulsory licensing (CL) system on the grounds of public welfare. Such laws may be used when patent exclusivity interferes with the public good. Unless there are extenuating circumstances, such as a national emergency or extreme urgency, that can be used to justify the issuing of a license at an earlier time, a CL may only be submitted three years following the grant of the patent. Three main arguments are provided for awarding the CL under Section 84 of the Patents Act. The patented idea is not now being used in Indian territory; the actual public demand for it has not been met; and it is not currently affordable to the general public. Contrarily, a CL can only be approved if the patent holder is fairly rewarded economically for the value of the permission.The procedures for awarding CL are under the TRIPS Agreement, as stated in the Doha Declaration on TRIPS and Public Health. Ministers of WTO Member States emphasized in the Doha Declaration, published in 2001, that the "TRIPS Agreement does not and should not prohibit members from adopting steps to protect public health." However, most importantly, Ministers concurred that the "Agreement may and should be read and implemented in a manner supportive of WTO members' responsibility to defend public health and, in particular, to facilitate access to medicines for all." The Declaration also reiterated that "each Member can award mandatory permits and have the discretion to set the criteria upon which such licenses are provided." [9]India has established limitations on CL with great caution. Following TRIPS, these clauses have only been used once, according to records. Sorafenib tosylate,

a medication used to treat cancer, was patented by Bayer Corporation. Bayer had to import enough products to meet demand because the product's asking price of Rs. 2,80,000 ($4600) needed to be revised. An authorization for sorafenib tosylate was requested by Natco Pharma Ltd. in India. A month's supply of medication from Natco is expected to cost Rs. 8,000 (about $130), a significant discount from Bayer Corporation's charges. The Controller of Patents decided that Bayer was not making the patented technology reasonably available to the general public in the Natco Pharma application ruling, and the applicant was given a non-exclusive license. [14]Implementation of the TRIPS Agreement by Indian Pharmaceutical Companies The Indian government set up a system for product patents to fulfill its obligations under the TRIPS Agreement. This action made life very difficult for generic companies, which had previously prospered in the absence of a product patent system. However, the Indian government used the TRIPS Agreement's latitude and implemented several protections to guarantee the survival of the generic firm. [10] The post-TRIPS patent environment caused India's pharmaceutical industry to develop at two different paces. The big national generic manufacturers significantly increased their value in the 1990s. Recently, it has been evident that growth has slowed for the industry and particular companies like Dr. Reddy's and Cipla. These titans contributed to the consolidation and growth of the Indian industry in the 1990s. The top two wealthiest companies were just revealed to be Sun Pharmaceutical and Lupin. These businesses expanded far more quickly than the industry standard, yet they could not stop the declining trend in growth rates. Between 2013 and 2014, Sun Pharmaceutical's net value roughly doubled, mostly due to the purchase of Ranbaxy Laboratories, the undisputed market leader for Indian generics, until the middle of the previous decade. One of the top 20 foreign business affiliates, Pfizer, was the only one with a consistent net worth rise in the new millennium.Of all the major industries in India, the pharmaceutical business has the greatest profitability ratio. It is important to note that the pharmaceutical business has seen earnings growth almost continuously. However, the pharmaceutical industry has outperformed other economic sectors despite major uncertainty brought on by changes to patent law.

Indian industry in world market

Since big pharma corporations were enfolded on exports than those in other sectors, the generic pharmaceutical business did much better in foreign markets. Early in the 1990s, a drive to strengthen the industry's export orientation commenced. It quickly gained momentum in later decades and was particularly clear for the major generic manufacturers in the sector.Overseas markets have recently become far more crucial to many enterprises than the domestic market. Cipla Ltd. and Dr. Reddy's Laboratories are two notable companies. Dr. Reddy's Laboratories earned an average of 74% of its sales in global markets between 2011 and 2017, compared to Cipla Ltd.'s nearly 51%. It's also important to realize that these companies have steadily increased their emphasis on exporting.In contrast, affiliates of international corporations operating in India do not participate in significant exports; their manufacturing facilities are increasingly employed to meet India's domestic demand. Since the middle of the previous decade, affiliates of the top multinational firms, such as GSK and Pfizer, have decreased their exports from India. In the last two decades, India's total trade in pharmaceuticals has grown from less than US$ 2 billion to more than US$ 27 billion. Robust export performance has climbed from a little over $1 billion in 1996 to over $20 billion in 2016. The pharmaceutical industry is one of the few manufacturing sectors whose net foreign currency earnings are always going up. During the last two years, when India's exports have been mostly unstable, the pharmaceutical business has been the only industry to see a steady rise in exports. In 1995-1996, more than half of Indian generic enterprises' formulation exports were destined mainly for Europe and Asia. Two decades later, the share of the two regions had dropped by a fifth due to an increase in exports to other regions, not a decline in the value of their exports. Exports to North America and Africa increased, while shipments to Europe and Asia decreased. North America was the largest market for Indian formulations in 2016, accounting for 41% of the total. The region's exports increased from $60 million in 1996 to more than $5 billion in 2016. The presence of Indian generic firms in Africa was equally notable. Between 2003 and 2016, Indian pharmaceutical exports to Africa increased nearly tenfold, from $270 million to over $3 billion. The largest market for Indian formulations is the United States (39% market share). This market has grown significantly from less than $300 million in 2005 to more than $5 billion in 2016. At the same time, the European Union's relative importance as a market for Indian generics fell.[11]The TRIPS Agreement has made the Indian pharmaceutical business work harder and focuses more on research and development, which has helped it move to the top of the GVC. Higher up the value chain requires constant change, new ideas, and more work. In the 1990s, Indian companies provided active pharmaceutical ingredients (API) and formulas, but that was the only part of the process in India. Indian companies now cover almost all of the

pharmaceutical GVC range, from developing new ideas to selling and distributing them.

In the GVC system, four updating types have been identified (see Figure 3).
Process improvement means making the way inputs are turned into outputs more efficient, and can be done by changing the production system or using better technologies.Available updating is the process of adding new functions or removing old ones to increase the total skill level of activities.Inter-sectoral upgrading happens when businesses in a cluster switch to a new way of making money.India's pharmacy industry joined the GVC for the first time as an API provider. It has changed into a company that sells ready-to-use amounts. India is today a source of both generic and brand-name drugs. The value of what India sells abroad is going up. At first, India's main products were antibiotics and painkillers. Now, A higher unit value indicates that a product has upgraded, moving to a more intricate line of products.

India sells more medicines with high added value, such as antihypertensive and anticancer drugs. These achievements show that the product has improved.[15]The value chain for generic drugs is different from that for branded drugs. Research and development (R&D) for making new medicines must involve people from different fields. Also, several Indian drug companies have entered the market for biopharmaceuticals. This event shows how progress is made in different fields.The firm's business skills determine how often and well upgrades are done. Transferring technologies requires learning because they are not obvious, and their basic ideas need to be better understood by most people. Before using

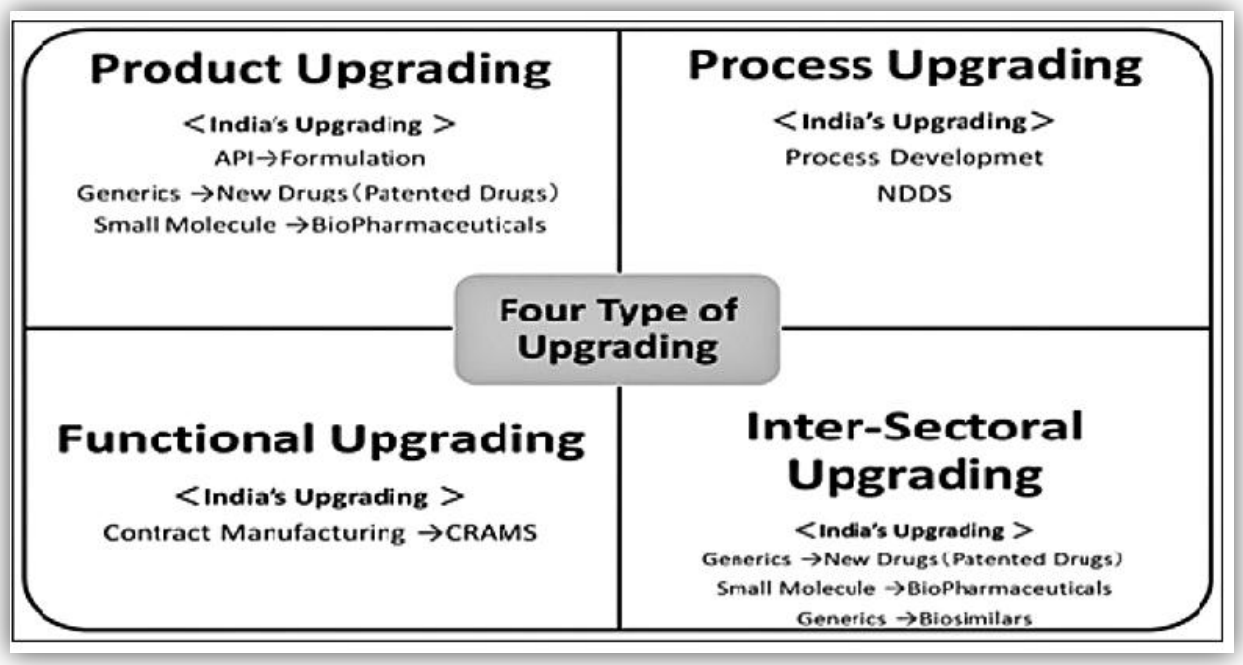


Figure 3 Four types of upgrading in GVC framework

this information in business operations and creating new business value through organizational and technological innovation, a company must first trends.

2. Conclusion

In an ever-shifting world of intellectual property protection, the Indian pharmaceutical industry faces considerable challenges. The flexibilities provided by the Indian Patents Act, which has provided some space to the manufacturers of generic medicines in the country, have been critically commented on by

understand the current rules, technology, and market

two of India's largest economic partners, namely, the United States and the EU.India is well known as patent maverick, whereas China as a naïve patent taker, especially in pharma invention. With Indian Patents Act utilizing the leeway left by the TRIPS Agreement to better suit its national interests and developmental needs, India's pharma industry is poised to further outperform its Chinese counterpart. [8] In support of this vision, the

Government of India is striving to create a robust IPR regime that can serve as the bedrock of innovative and competitive India. Indeed, many countries are closely observing the evolution of Indian IPR regime to see how it further leverages the flexibilities offered by TRIPS to advance its own socioeconomic goals while simultaneously promoting its innovation ecosystem and protecting the legitimate business interests of MNCs. Thus, India's patent reforms are having a global impact.Due to the severe difficulties with the TRIPS Agreement, Indian pharma businesses have developed new business strategies. They have updated their R&D approach in addition to increasing their R&D investment. They are launching commercially successful products that use new chemicals and NDDS. Indian pharmaceutical businesses have improved their standing in the international pharmaceutical market by demonstrating strong R&D capabilities. They have been pursuing a cooperation strategy with big pharmaceutical companies since the late 1990s. Through international strategic alliances with multinational pharmaceutical businesses, Indian pharmaceutical enterprises have participated in the pharmaceutical GVC throughout the post-TRIPS era. The TRIPS Agreement gave Indian pharmaceutical companies additional development opportunities, while GVC's participation encouraged technology advancement and transfer. By applying cutting-edge technologies and utilizing their significant R&D capabilities, Indian pharmaceutical businesses are improving in the GVC. This upgrade has spurred the growth and development of the Indian pharmaceutical industry in the post-TRIPS era.[15]

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