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BALANCING PATENT AND PUBLIC HEALTH - A LEGAL APPRAISAL OF RELEVANCE OF TRIPS AND DOHA DECLARATION IN INDIAN PHARMACEUTICAL INDUSTRY

Anushree Mukte
Research Scholar, Post Graduate Teaching Department of Law (Autonomous),
Rashtrasant Tukadoji Maharaj Nagpur University (RTMNU), Nagpur.

Abstract
This paper examines the impact of the TRIPS Agreement and the Doha Declaration on pharmaceutical patents in India, analyzing legal frameworks, compulsory licensing, and innovation implications. It highlights how these mechanisms influence access to affordable medicines, ensuring public health while fostering innovation within the pharmaceutical sector. Through statistical insights and case studies, including significant legal battles, the research underscores the balance between patent protection and the need for accessible healthcare in developing countries. Ultimately, it emphasizes the importance of sustainable patent policies in enhancing both public health and global pharmaceutical competitiveness.

Keywords: TRIPS Agreement, Doha Declaration, pharmaceutical patents, compulsory licensing, public health.

1. Introduction

There has long been controversy around the relationship between intellectual property rights and public health, especially with reference to the pharmaceutical industry. The global discourse surrounding intellectual property rights has been significantly shaped by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration that followed. An important difficulty is striking a balance between patent protection and the availability of reasonably priced medications for countries such as India, whose pharmaceutical industry is expanding at a rapid pace. This essay seeks to assess the Doha Declaration's and TRIPS's legal implications for the Indian pharmaceutical industry, with particular attention to how they affect public health and patent law.

1.1 The History and Purposes of the TRIPS Agreement

In 1995, the WTO took charge of the implementation of the TRIPS Agreement. Its goal was to ensure that minimum protection requirements were set for different types of intellectual property, including patents, by standardizing intellectual property laws among participating nations. TRIPS was designed, among other things, to encourage innovation by giving inventors the temporary exclusive right to use their inventions. Within the pharmaceutical industry, patents give businesses the ability to recoup their R&D costs by granting exclusive rights to produce and

market novel medications. However, worries were raised about the possible negative consequences on the availability of reasonably priced medications, especially in developing nations like India (Correa, 2000). India was required to amend its domestic legislation in order to comply with the TRIPS Agreement as a WTO member. The Indian Patent Act of 1970 did not permit patents on medicinal items and only permitted patents on processes prior to TRIPS. This made it possible for Indian pharmaceutical companies to use different production techniques to create generic versions of patented drugs. As a result, India became the world leader in providing reasonably priced generic medications, gaining the moniker "*The Pharmacy Of The Developing World*" (Chaudhuri, 2005). However, TRIPS necessitated a fundamental change, and by 2005, India had implemented product patents in the pharmaceutical industry (Watal, 2001). The Doha Declaration upheld TRIPS's intrinsic flexibility, enabling nations to give public health top priority and improve drug availability. It made it clear that member states might adopt policies to protect public health, like using parallel imports or granting mandatory permits, without being prevented by TRIPS (Love, 2002).

The Doha Declaration went into further detail on this, highlighting the possibility that permits could be required in cases of public health emergencies like the HIV/AIDS epidemic. India's approach to striking a balance between patent rights and the necessity of guaranteeing access to reasonably priced medications has been greatly impacted by the Doha Declaration (Löfgren, 2007).

1.2 Effects on the Pharmaceutical Industry in India

Since the generic drug was made accessible at a significantly lower cost than the original version, the compulsory license was granted on the grounds that the proprietary drug was expensive for the majority of patients in India (Gopakumar, 2013). Furthermore, patent opposition provisions are included in India's patent law, enabling third parties to contest the legitimacy of a patent both before and after it is awarded. This has been a vital weapon in stopping "evergreening," or the issuance of frivolous or unwarranted patents. A notable example is the well-known Novartis AG v. Union of India (2013) case, in which the Indian Supreme Court rejected a patent application for an altered version of the cancer medication Glivec, concluding that the modification did not satisfy Indian legal requirements for patentability (Basheer, 2014). This ruling strengthened India's resolve to stop evergreening practices and to advance the availability of reasonably priced medications. India has been the target of criticism from the US under its Special 301 Report, which keeps tabs on foreign IP policies. India has frequently been on the U.S. "Priority Watch List," with the country's use of compulsory licensing and patent opposition being cited as reasons (Raghavan, 2015). India may investigate fresh approaches in the future to foster innovation in its own pharmaceutical sector, all the while maintaining the focus on the availability of reasonably priced medications. Increased R&D spending, public-private collaborations, and the creation of fresh approaches to finance pharmaceutical innovation are a few examples of this (Baker & Avafia, 2011).

2. Review of the Literature

2. 1. TRIPS' Development and Effect on Worldwide Pharmaceutical Patents

All World Trade Organization (WTO) members are required to offer minimum standards of patent protection, especially for pharmaceuticals, under the TRIPS Agreement, which serves as a comprehensive framework for intellectual property protection (Watal, 2000). Pharmaceutical products must adhere to a 20-year patent period under TRIPS, which gives patent holders exclusive rights and is meant to encourage innovation. But in developing nations, this exclusivity has unintentionally restricted access to necessary medications (Correa, 2014). According to academics like Sell (2003), multinational pharmaceutical companies have profited greatly from TRIPS at the price of global public health, especially in low-income areas.

2.2 The Doha Declaration's Significance for Public Health

WTO made clear that nations could guarantee access to necessary medications by utilizing TRIPS flexibilities such parallel importation and mandatory licensing (Ho, 2011). The Doha Declaration's effects have been studied by a number of writers, especially in nations like India. According to Love (2002), the Declaration was a turning point in public health policy because it gave nations wishing to obtain less expensive generic copies of proprietary medications legal certainty.

2.3 Pre- and Post-TRIPS Indian Patent Law

Indian patent legislation was created to promote the manufacture of generic medications prior to TRIPS. Process patents were made possible by the Patents Act of 1970, allowing Indian pharmaceutical businesses to produce medications using non-traditional methods without violating product patents (Chaudhuri, 2005). Thanks to this approach, India's generic pharma business grew, positioning it as a major provider of reasonably priced medications to low- and middle-income nations (Lanjouw, 1998).
Following TRIPS, India had to move to a product patent system by 2005, which raised questions about how this might affect the availability of reasonably priced medications (Watal, 2001). Chaudhuri (2005) emphasizes that the pharmaceutical business in India, which had prospered under the process patent system, faced serious hurdles as a result of this change. The product patent regime raised the price of new medications by giving patent holders exclusive rights, which raised worries about the effects on public health in a nation where a sizable portion of the population lives in poverty (Reichman, 2009).

2.4 Mandatory Licensing

The purpose of implementing mandatory licensing regulations under TRIPS (Article 31) was to provide a safety net for nations experiencing public health emergencies. A lot of research has been done on India's usage of forced licensing; one of the most often cited cases is Natco Pharma v. Bayer (Gopakumar, 2013). The inability of the cancer treatment Nexavar to be affordable and the requirement to guarantee more public access were the reasons given by the Indian government to Natco Pharma for the mandatory license. Basheer (2014) claims that this case showed India's readiness to use TRIPS flexibilities to strike a compromise between the needs of public health and patent rights. Some academics, like Sampath (2005), contend that even with the potential advantages for public health, India has only occasionally and cautiously used compulsory licensing. Nonetheless, the Nexavar case's effective application of this approach has sparked additional conversations over its potential to improve access to life-saving medications in India.

2. 5. Indian Patent Oppositions and Evergreening

"Evergreening," the practice of firms making minor changes to already-approved pharmaceuticals in order to prolong their patent monopolies, is a significant problem in the field of pharmaceutical patents. Section 3(d) of the Indian Patents Act prohibits the patenting of incremental advances unless they show a substantial improvement in medicinal efficacy. The impact of the Novartis case (Novartis AG v. Union of India, 2013) on Indian public health and patent law has been extensively addressed in scholarly literature (Basheer, 2013). In this instance, the Indian Supreme Court rejected a request for a patent on a modified form of the cancer medication Glivec, finding that the revised formulation fell short of the necessary standard of increased therapeutic efficacy. By prohibiting the practice of evergreening, this historic judgment strengthened India's standing as a champion of accessible, reasonably priced healthcare (Kapczynski, 2013).

2.6. The Effects of India's Patent Policy Worldwide

The world has been greatly impacted by India's patent policy, especially the low- and middle-income nations that depend on Indian generics to meet their medical needs (Löfgren, 2007). More than 80% of the antiretroviral medications used to treat HIV/AIDS in underdeveloped nations are supplied by the Indian pharmaceutical sector (Chaudhuri, 2005). This has made India a major participant in international public health, and its patent laws continue to have an impact on discussions about intellectual property rights and global access to medications (Flynn, 2008). Baker and Avafia (2011) state that other developing nations attempting to negotiate the obstacles presented by TRIPS can take a cue from India's approach to striking a balance between patent rights and public health. For other countries tackling comparable problems with intellectual property and public health, the nation's aggressive approach to forced licensing and patent resistance offers a useful case study.

3. Research Gap

There is a dearth of study concerning the long-term socio-economic implications on the availability of reasonably priced medications and innovation within India's pharmaceutical industry. Furthermore, more research is necessary to fully understand how India's policy decisions are impacted by the changing global trade environment, particularly in light of the growing public health emergencies.

4. Research Objectives

i. To examine how the Doha Declaration and the TRIPS Agreement affect the legislative and policy frameworks controlling pharmaceutical patents in India.
ii. To evaluate how TRIPS flexibilities, such mandatory licensing, affect India's ability to obtain reasonably priced medications.
iii. To assess how India's patent laws may affect innovation and the world market for pharmaceuticals.

5. Methodology

The present study employed a technique aimed at evaluating the legal significance of the Doha Declaration and the TRIPS Agreement within the framework of the pharmaceutical sector in

India. Using a qualitative research methodology, the study concentrated on a thorough analysis of academic, legal, and policy papers. A range of secondary sources, including case studies of significant legal conflicts like the Novartis and Natco Pharma cases, as well as international legal frameworks like the Doha Declaration, TRIPS, and India's Patents Act, were used to gather data. The World Trade Organization (WTO) and allied entities' reports, legal commentary, and scholarly articles all shed light on how patent law affects public health. The study used content analysis to look at how India balanced access to reasonably priced medications with patent protection by making use of TRIPS flexibilities like compulsory licensing and patent opposition. Important themes and trends were found, with an emphasis on how India strategically employs legislative tools to protect public health. The analysis also took into account the consequences for the rest of the world, with a focus on India's contribution to the manufacturing of generic medications for underdeveloped nations. The results were placed in the perspective of the larger international discussion on intellectual property rights and public health.

6. Research Findings

6.1 An examination of the legislative and policy frameworks pertaining to pharmaceutical patents in India under the Doha Declaration and the TRIPS Agreement

The WTO Agreement on TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health serve as the foundation for the legal and policy frameworks that control pharmaceutical patents in India. TRIPS, which was adopted in 1994, aims to standardize intellectual property (IP) regulations across WTO members, including India. Members of the agreement were obliged to adhere to minimal criteria for a variety of intellectual property, including patents related to pharmaceuticals. India was compelled to alter the Patents Act of 1970 in order to comply with the TRIPS Agreement as a signatory. It accomplished this in 2005 by adding product patents for pharmaceuticals.

India's pharmaceutical patent regime saw a significant change thanks to the TRIPS Agreement, which recognized product patents in addition to process patents. Wide-ranging effects resulted from this change for India's rapidly expanding generic drug market, which was previously known as the "pharmacy of the developing world" due to its capacity to provide reasonably priced medications (Chaudhuri, 2005). Indian Patent Regime Prior to TRIPS

The Indian Patent Act of 1970 only permitted process patents in the pharmaceutical industry; product patents were prohibited prior to TRIPS. This implied that Indian businesses may use different production techniques to create generic versions of patented medications. India's pharmaceutical sector flourished due to the lack of product patents, particularly in the generic drug market, which made India a global leader in providing poor countries with affordable medicines. According to the Indian Brand Equity Foundation (IBEF), as of 2020, India supplied more than 60% of the world's vaccination demand and 20% of the world's supply of generic pharmaceuticals.

With the Patents Act of 1970, the Indian government made public health a higher priority than patent protection, which contributed to the continued availability of reasonably priced medications. In particular, for serious illnesses like HIV/AIDS, malaria, and tuberculosis, this legislative framework was essential to India's emergence as a major global provider of pharmaceuticals (Chaudhuri, 2005). The regulation was a major factor in enabling Indian

pharmaceutical companies to make less expensive versions of patented medications by reverse engineering them, which they subsequently marketed to underdeveloped nations. For example, by 2014, more than 80% of the antiretroviral (ARV) medications used to treat HIV/AIDS in low-income countries came from India (UNAIDS, 2014).

6.2 Post-TRIPS: India's Obligations and Difficulties

An important change in policy was brought about by India's ratification of the TRIPS Agreement. Product patents were added to the Indian Patents Act in 2005, which made the domestic pharmaceutical market in India more difficult to operate in. The new law prohibited Indian businesses from producing generic versions of patented medications until the patent expired, usually after 20 years. Because the introduction of product patents increased the cost of patented treatments, this development prompted worries about the affordability of novel medicines (Watal, 2001).

India included a number of safeguards in its patent system to guarantee access to reasonably priced medications even in the face of these worries. For instance, the Indian Patents Act's Section 3(d) attempts to stop "evergreening," a practice in which businesses in the pharmaceutical industry prolong patent protection through small changes to already-approved medications. The Indian Supreme Court refused a patent for a modified version of the cancer medicine Glivec in the historic Novartis AG v. Union of India (2013) case, finding that the modification did not meet the enhanced therapeutic efficacy criteria under Section 3(d) of the Indian Patent Act (Basheer, 2014). This decision reaffirmed India's resolve to prohibit unwarranted patent monopolies that can impede the availability of reasonably priced medications.

6.3 Mandatory Licensing in accordance with the Doha Declaration and TRIPS

Compulsory licensing is a crucial flexibility granted by TRIPS. It permits situations of national emergency or when the product is not reasonably priced. The requirements for using compulsory licensing are outlined under Article 31 of TRIPS, and the Doha Declaration of 2001 reiterated that the use of this mechanism was warranted in light of public health emergencies including HIV/AIDS, TB, and malaria.

India has used compulsory licensing to combine the needs for public health and patent protection in an effective manner. The case that stands out the most is Natco Pharma Ltd. v. Bayer Corporation (2012), in which India granted the cancer medication Nexavar its first mandatory license. With a monthly cost of about INR 280,000 (USD 3,700) for the trademarked form of Nexavar from Bayer, most Indian patients could not afford it. Natco Pharma was given a mandatory license by the Indian government to manufacture a generic version of the medication, which was sold for a much lower monthly cost of INR 8,800 (USD 110) than the original (Gopakumar, 2013). In order to address the problem of excessive drug pricing in India, notably for life-saving medications, this case established a precedent for the use of compulsory licenses.

6.3 The Public Health Strategy of India and the Doha Declaration

For developing nations like India, the Doha Declaration on the TRIPS Agreement and Public Health was a turning point because it made it clear that member states should be able to defend public health without being hindered by TRIPS. The statement stressed that nations could guarantee access to medications, especially in times of public health emergency, by using parallel

imports and mandatory permits. For India, which over the past 20 years has experienced numerous public health concerns, this flexibility has been crucial.

6.4 Oppositions to Patents: A Legal Protection

Patent opposition provisions, which enable third parties to contest a patent's validity both before and after it is granted, are also included in India's patent law. This process has shown to be an essential instrument in stopping the issuance of pointless patents that can hinder the development of reasonably priced generic substitutes. Sections 25(1) and 25(2) of the Indian Patents Act describe the pre-grant and post-grant opposition methods that enable interested parties to challenge patent applications that fail to satisfy the standards of novelty, non-obviousness, or industrial applicability. The Novartis case is among the most well-known instances of patent opposition in India. Several health campaigners and Indian pharmaceutical businesses protested Novartis's patent application for an upgraded version of their cancer medication Glivec. The Indian Supreme Court later upheld the Indian Patent Office's rejection of the application, which was based on the modification's failure to comply with Section 3(d) standards. This ruling has been heralded as a historic success for the availability of reasonably priced medications, especially in developing nations (Kapczynski, 2013).

6.5 The Effects of India's Patent Laws Worldwide

Global ramifications of India's patent policies are evident, especially for low- and middle-income nations that depend on Indian generics to meet their medical needs. Despite the limitations imposed by the global patent regime, India has been able to continue producing and exporting generic medications thanks to its judicious use of TRIPS flexibilities. India supplied more than 40% of the generic pharmaceutical demand in the United States and 25% of the demand in the United Kingdom as of 2020, making it the world's top supplier of generic medications (IBEF, 2020). Furthermore, the Pharmaceutical Export Promotion Council (2020) reports that India's pharmaceutical exports were valued at USD 24.6 billion in 2020, indicating its significant contribution to the global supply chain for reasonably priced pharmaceuticals.

6.6 Evaluating TRIPS Flexibilities' Effect on India's Access to Inexpensive Medicines with a Particular Attention to Compulsory Licensing

An Overview of TRIPS and Accessibility Options for Pharmaceuticals

All parties were obliged to abide by minimal requirements for several types of intellectual property, including patents on pharmaceuticals, as part of the TRIPS Agreement. This presented a serious problem for nations like India, where the exorbitant expense of copyrighted medications may prevent some people from getting access to life-saving medications, particularly the impoverished and vulnerable. Acknowledging the problems with strict patent laws for public health, the TRIPS Agreement contains a number of flexibilities, such as parallel imports, mandatory licensing, and exceptions for less developed nations. The Doha Declaration on the TRIPS Agreement and Public Health (2001), which stressed that TRIPS should be construed in a way that supports member nations' rights to safeguard public health and encourage access to cheap medicines, defined and reaffirmed these flexibilities.

6.7 Mandatory Licensing as a TRIPS Option

Compulsory licensing is one of the most important flexibilities granted under TRIPS. If a patented drug is too expensive or there is a public health emergency, the government may, under Article 31 of TRIPS, approve the production of the product without the patent holder's consent. Complying with international patent commitments, countries such as India can guarantee their population's access to reasonably priced pharmaceuticals through the system of compulsory licensing. Adopted in 2001, the Doha Declaration went on to state that governments should be able to take action to protect public health without being hindered by the TRIPS Agreement. In particular, the declaration confirmed that nations had the authority to grant licenses under penalty of law in order to combat public health emergencies including malaria, HIV/AIDS, and TB. In India, compulsory licensing has developed into a crucial weapon for policymakers seeking to increase access to reasonably priced medications, especially for life-saving medications that would otherwise be unaffordable because of patent protection.

6.8 The Background in India: Both Pre- and Post-TRIPS

Pharmaceutical process patents were permitted under India's Patents Act of 1970 prior to TRIPS, but product patents were not. This meant that by using different production techniques, Indian businesses could lawfully create generic versions of copyrighted medications. India's pharmaceutical business flourished due to the lack of product patents, especially in the generic medication market. This earned India the title of "pharmacy of the developing world." Because the Indian Patents Act of 1970 allowed Indian pharmaceutical businesses to make generic versions of copyrighted treatments at much cheaper prices, it considerably contributed to the availability of affordable medicines. India was compelled to modify its patent rules in order to comply with TRIPS once it signed the pact. Pharmaceutical product patents were added to India's Patents Act in 2005, which sparked worries about possible price increases for medications. However, the 2005 amendment kept a number of important TRIPS flexibilities, such as requirements for compulsory licensing and measures to stop "evergreening," which is the practice of prolonging patent protection by making slight changes to already-approved medications. India has been able to maintain the population's access to necessary medications by striking a balance between the demands of public health and patent protection thanks to these flexibilities.

6.9 Important Cases of Compulsory Licensing in India

India has improved access to necessary medications by efficiently utilizing the regulations pertaining to compulsory licensing. The case that stands out the most is Natco Pharma Ltd. v. Bayer Corporation (2012), in which India granted the cancer medication Nexavar (sorafenib tosylate) its first mandatory license. At over INR 280,000 (USD 3,700) each month, Nexavar—a medication used to treat kidney and liver cancer—was out of reach for the great majority of Indian patients. Nexavar was patented by Bayer Corporation, but due to its exorbitant cost, the Indian government gave Natco Pharma a compulsory license, which enabled the business to manufacture and market a generic version of the medication for just INR 8,800 (USD 110) a month. Section 84 of the Indian Patents Act, which permits compulsory licensing in cases where the patented product is not reasonably affordable for the general public, served as the foundation for this historic ruling. According to Gopakumar (2013), the case established a precedent for the use of compulsory licensing to meet public health requirements in India, namely for life-saving

pharmaceuticals. The price of Nexavar decreased by more than 97% once the mandatory license was issued, greatly enhancing cancer patients' access to the medication in India.

6.10 The Effect of Compulsory Licensing on the Economy

Compulsory licensing has a significant impact on India's ability to get reasonably priced medications. An estimated 80% of Indian cancer patients who would not have been able to buy Nexavar at Bayer's original pricing were able to do so once the medicine was made available at a mandatory license (Gopakumar, 2013). The case also showed how committed India is to using TRIPS flexibilities to put public health ahead of pharmaceutical patent monopolies. India has contemplated mandatory licensing for a number of medications since the *Nexavar* case, including those used to treat hepatitis C and HIV/AIDS. The prospect of mandatory licensing has in numerous instances incentivized patent holders to engage in negotiations with the Indian government or extend voluntary licenses to Indian generic manufacturers at reduced rates, therefore circumventing the necessity of mandatory licensing and concurrently bringing down drug prices. For instance, in 2014, Gilead Sciences and a number of Indian pharmaceutical firms came to a voluntary licensing deal that allowed Gilead to manufacture and market generic copies of Sovaldi, the company's treatment for hepatitis C, at a significantly lower cost than the original medication. As per Sampath (2015), Indian producers were able to offer sofosbuvir for as little as INR 19,900 (USD 270) for a 12-week course, which was significantly less than the about USD 84,000 pricing in the United States. The accessibility of therapy for millions of hepatitis C patients has been greatly facilitated by the availability of reasonably priced generic forms of *Sofosbuvir* in India and other developing nations.

6.11 The Function of Patent Opposition in Improving Medication Access

Apart from mandatory licensing, the patent legislation in India incorporates clauses for patent opposition, enabling external parties to contest the legitimacy of a patent both before to and following its issuance. This process has been crucial in preventing the issuance of pointless patents, especially when pharmaceutical companies want to renew their patents. In India, Novartis AG v. Union of India (2013) is one of the most notable cases of patent opposition. Novartis applied for a patent for an improved version of its cancer medication Glivec, but pharmaceutical companies and Indian health activists rejected the application, claiming the improved version did not satisfy Section 3(d) of the Indian Patents Act's requirements for novelty or increased therapeutic efficacy. In the end, Novartis' patent application was denied by the Indian Supreme Court, preventing the business from expanding its monopoly on Glivec and permitting Indian businesses to carry on manufacturing generic copies of the medication at significantly reduced costs (Basheer, 2014). An important illustration of how India's patent opposition system has been applied to maintain the affordability of necessary medications is the Novartis ruling. India has been able to reduce the effects of evergreening and keep its position as a global leader in the manufacture and export of reasonably priced generic medications by opposing unnecessary patents.

6.12 The Worldwide Consequences of India's Mandatory Licensing and Patent Opposition Procedures

Significant global ramifications have resulted from India's use of TRIPS flexibilities, notably compulsory licensing, especially for low- and middle-income nations that depend on Indian generics to meet their healthcare needs. India supplied more than 40% of the generic pharmaceutical demand in the United States and 25% of the demand in the United Kingdom as of 2020, making it the world's top supplier of generic medications. In many developing nations, access to reasonably priced medications has been made possible by India's pharmaceutical exports, which were estimated to be worth USD 24.6 billion in 2020 (Pharmaceutical Export Promotion Council, 2020). Furthermore, India's strategy of compulsory licensing has served as a model for other developing nations looking to strike a compromise between the requirements of public health and patent protection. Following India's example, nations including Brazil, Thailand, and South Africa have imposed obligatory licenses in order to handle public health emergencies and enhance access to reasonably priced medications.

6.13 Pre-TRIPS Era: Process Patents and Generic Manufacturing: Assessing the Effects of India's Patent Laws on Innovation and the Global Pharmaceutical Market

The Indian Patents Act of 1970, which outlawed the patenting of medicinal products, significantly changed the patent landscape in India. This legal structure only permitted process patents, which meant that a business could only patent the technique of producing a medication—not the medication itself. Indian pharmaceutical firms were thus able to lawfully reverse-engineer and produce patented medications utilizing different procedures. As a result, production costs were drastically lowered, allowing Indian businesses to provide reasonably priced generics to both the domestic and international markets.

The process patent system in India was essential in providing low- and middle-income nations with access to necessary medications. Product Patents in the Post-TRIPS Era: Their Effect on Innovation Following its entry into the WTO's TRIPS Agreement in 1995, India was mandated to enact pharmaceutical product patents by the year 2005. India's patent system underwent a dramatic change with the introduction of product patents, which has various ramifications for medical innovation and patient access.

1. TRIPS was primarily designed to encourage innovation by giving pharmaceutical companies better intellectual property protection. The idea behind product patents is to incentivize pharmaceutical companies to engage in the costly and high-risk process of medication discovery and development by giving the patent holder exclusive rights. Product patents have, nevertheless, had a mixed effect on innovation in India.

2. Patent Battles and Evergreening: More patent litigation resulted from enhanced patent protections, which in turn promoted higher investment in innovation. The practice of "evergreening," in which pharmaceutical corporations try to prolong the life of their patents by making slight changes to already-approved medications, has been one of the main causes for concern. Section 3(d) of the 2005 Patents (Amendment) Act in India was enacted as a response

to this. It states that new versions of recognized compounds cannot be patentable unless they show appreciable improvements in efficacy. India's strong stance against evergreening was underscored by the Supreme Court's ruling in Novartis AG v. Union of India (2013), wherein Novartis' patent application for an updated version of the cancer medicine Glivec was denied (Basheer, 2014). This clause has been praised for providing a crucial safety net to guarantee that generic drugs are available at reasonable prices while also honoring real pharmaceutical innovation.

3. The Function of Mandatory Licensing: The provision for forced licensing is another important flexibility that has been kept in India's patent system. The government may, under specific circumstances, permit the manufacture of generic versions of proprietary medications without the patent holder's approval. The most famous instance of this is the mandatory license for the cancer medication *Nexavar*, which was priced by Bayer at INR 280,000 (USD 3,700) a month, that was given to Natco Pharma in 2012. Because Natco was able to create the medication at a considerably reduced cost, more people will have access to it (Gopakumar, 2013). Compulsory licensing has been vital in keeping essential medicines accessible and affordable for the Indian populace, even though it may deter investment from global pharmaceutical companies.

7. Conclusion

India's patent laws have influenced pharmaceutical innovation and the world market for pharmaceuticals in a significant and varied way. Public health has been prioritized despite the fact that product patents under TRIPS have encouraged Indian pharmaceutical companies to invest more in R&D. This is because the country is committed to ensuring that access to affordable medicines is protected, as evidenced by laws like Section 3(d) and compulsory licensing. As the primary provider of generic medications, especially to low- and middle-income nations, India has cemented its standing as the "pharmacy of the developing world.". But even with the development of bio-similars and incremental innovation, India continues to struggle with the discovery of novel drugs, which calls for increased funding for cutting-edge R&D facilities. India has created a precedent for prioritizing access to life-saving medications and affected policy discussions in other emerging countries due to its approach to striking a balance between intellectual property rights and public health concerns. In order to preserve its leadership in global health equity, India will need to keep improving its patent laws in the future.

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