PHARMACEUTICAL PATENTS IN INDIA: LEGAL DYNAMICS AND ANALYSIS ON GLOBAL INFLUENCES

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Abstract

India's pharmaceutical industry has grown as a lucrative and technologically advanced sector, with constant growth in the last few decades. With a focus on securing significant expenditures in research and development, factors such as intellectual property rights have significantly become important in today's globalized world. In the pharmaceutical industry, patents are by far the most prevalent form of intellectual property. The Patents Act of 1970 defines both patentable and non-patentable objects, shaping the landscape for innovation and competitiveness in the industry. This paper addresses several aspects of the Patent Act and examines how the Indian patent system evolved significantly since the signing of the Trade-Related Areas of Intellectual Property Rights (TRIPS) agreement in 1995. The TRIPS agreement forced India to change its patent system from one based on processes to one based on products, which had an impact on the pharmaceutical industry's dynamics. This paper further delves into the global influence on Indian pharmaceutical patents, focusing on the impact of global pressures. Furthermore, it elucidates the factors involved in granting pharmaceutical patents in India and gives a thorough analysis of various types and elements involved in the awarding of pharmaceutical patents in India. In addition, the article elucidates the transfer of patent rights in the pharmaceutical industry and delves into the intricacies involved in it. The paper also includes a critical analysis of the consequences of pharmaceutical patenting on the Indian healthcare system, with a focus on its outcomes for patients. This comprehensive analysis takes into account the legal, economic,

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and sociological aspects and offers a clear grasp of the complex issues related to pharmaceutical patents in the country.

***Keywords**: patent, pharmaceutical patents, TRIPS, patent rights*

Introduction

Intellectual property (IP) refers to intangible assets created via human intellectual effort. Intellectual Property Rights (IPRs) exist as a result of the creation of intellectual property, and these rights are awarded to the creator (inventor, author, etc.). Patents, trademarks, industrial designs, geographical indications, and copyright are among the most prevalent kinds of intellectual property rights in India. The protection of intellectual property, especially within the pharmaceutical industry, is a widely discussed issue in developing nations. Within the pharmaceutical sector, patents emerge as the most prevalent and commonly used type of intellectual property.

India has had a unique status among developing countries because of its strong generic pharmaceutical sector, which was able to provide medications at exceptionally low costs all over the world. Nonetheless, significant changes in the patent system throughout time have altered the circumstances in which the Indian pharmaceutical sector first emerged.

This paper explores the implications of India's evolving patent laws with a particular emphasis on the pharmaceutical industry. The legal framework for patents in India has experienced a significant transformation. During the colonial era (1856–1947), the laws were protective of pharmaceutical patents. However, from 1972 to 2005, the laws were designed to foster the development of domestic industries by removing pharmaceuticals from patent protection. In following the global intellectual property system's requirements, the law put into effect in 2005 restored patent protection for pharmaceutical items. The article also analyzes the impact of the TRIPS Agreement on the Indian pharmaceutical sector and briefly discusses the intricacies of the process of the grant of patents in the pharmaceutical sector. It also provides insight into the ramifications of the growing patent system on the patients and the country's healthcare sector.

Evolution of Patent Law in India

Patents are granted to protect inventions. An exclusive right awarded by the government to the individual who files an innovation application is known as a patent. The creator or any other person or business they designate may pursue a patent. It is the right to stop others from developing, using, putting up for sale, importing, or selling the innovation without permission. When someone applies for or receives a patent, the government and the applicant or inventor

agree that, following full disclosure of the concept, the government will have the only right to protect the innovation for a set length of time. Patenting, then, offers an alternative to keeping inventions a secret when it comes to protection. A patent offers a technological solution to a particular technical issue, and patent protection is only granted to innovations that satisfy certain requirements. A patent can only be kept for a maximum of twenty years after the date the application was filed and can only be enforced in the nation where it is awarded because it is a territorial right. As such, the exclusive country in which to pursue legal action against patent infringement or violation occurs.[1]

Patent laws under the British rule

During the British colonial era, which came to an end in 1947 with India's independence, the country approved its first patent laws in 1856. Although the patent regulations changed during the colonial era, they always allowed for the patenting of pharmaceutical products. The bulk of issued patents during this period went to foreigners. During India's independence, multinational corporations (MNCs) dominated the pharmaceutical sector, with minimal participation from domestic businesses.

Patent laws after independence (1947-1995)

The government of India started drafting new patent rules after the country gained its independence in 1947, hoping to encourage the expansion and development of the pharmaceutical sector there. Twenty-five years were spent in the planning. After a series of expert reviews and legislative debates, The Patents Act of 1970 eventually came into effect in 1972. The Patents Act of 1970 imposed significant limitations on patent rights in an attempt to encourage indigenous inventions and guarantee their commercial production in India.[2] First and foremost, patent protection was not available for pharmaceutical products. Second, businesses were only permitted to patent a single pharmaceutical production process; they were not permitted to stifle competition by securing patents for all practical means of creating a medicine. Third, the fourteen years for patents pertaining to pharmaceutical processes was shortened to five years from the date of filing or seven years from the date of patent issue, whichever came first. As a fourth issue, the Act also placed onerous "compulsory licensing" regulations on patents related to pharmaceutical treatments. These patents were transformed

[1] Vipin Mathur, "Patenting of Pharmaceuticals: An Indian Perspective" 4 International Journal of Drug Development & Research 28(2012).
[2] The Patents Act, 1970 (Act 39 of 2000), s. 83.

into "licenses of rights," allowing anybody to use the method in return for a royalty, after three years from the date of the patent grant.[3] To sum up, pharmaceutical procedures were protected for five years if no royalty was given, and only for three years if a royalty was paid. In contrast, pharmaceutical products were not covered at all. [4]

India's pharmaceutical business was greatly impacted by the lack of product patent protection, especially in the areas of agrochemicals and pharmaceuticals. Reverse engineering of medications that are unprotected in India but patentable as products throughout the industrialized world has become significantly more skilled as a result of this.

As a result, the Indian pharmaceutical sector grew significantly, producing more reasonably priced indigenous substitutes for a variety of patented medications. After international patents expired, the industry aggressively entered the worldwide market by releasing generic copies of these medications. In addition, the Patents Act was passed to improve patient access to pharmaceutical drugs and to set up several safeguards against patent infringement.[5]

Post-TRIPS patent laws in India (1995-2005)

India signed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and became a founding member of the World Trade Organization (WTO) in January 1995. TRIPS allowed India, a developing country without developed pharmaceutical product patent laws at the time, a 10-year transition period that ended in January 2005. During this interim time, this allowed India to develop legislation around pharmaceutical patents.[6]

India changed its patent laws in 2002 to comply with TRIPS requirements. All inventions, including patents for pharmaceutical products, would now have a 20-year patent life after the transition period ends. These revisions included new language regarding required licenses as well. Under these conditions, an application for a compulsory license may be filed three years following the patent's issuance if the invention is not produced or manufactured in India if the invention does not meet the reasonable needs of the public, or if the invention is not reasonably priced.[7] Moreover, the law requires immediate, compulsory licensing when the government declares a public health emergency, allows the product to be used for noncommercial purposes

[3] Katherine Connor Linton, Nicholas Corrado, "A "Calibrated Approach": Pharmaceutical FDI and the Evolution of Indian Patent Law" 1 Journal of International Commerce and Economics 4(2007).
[4] Ibid.
[5] Business Briefing: Pharmatech, "Patents and the Indian Pharmaceutical Industry"46(2002).
[6] Trade-Related Aspects of Intellectual Property Rights, 1994, Art. 65.4.
[7] The Patents (Amendment) Act, 2005(Act 15 of 2005), s.84.

in the public interest, or intends to export the product to a country whose manufacturing capacity is insufficient to address public health concerns.[8] Of all the patent systems worldwide, Indian law has the most extensive compulsory licensing obligations. Because of this, multinational pharmaceutical companies are rather concerned about them; nonetheless, as of right now, no compulsory licenses have been issued under the new law. An important turning point in India's TRIPS implementation occurred in January 2005 when the country's statute had to be changed to allow for patent protection for pharmaceutical items, and the transition period was over. According to officials in the Indian government and industry, India is currently using a "calibrated approach" to intellectual property protection to strike a balance between public health, drug accessibility, and domestic industry interests. India has created an intellectual property framework that balances national priorities with recognition of the demands of the international intellectual property system.[9]

Process of Grant of Pharmaceutical Patents In India

Since the World Trade Organization (WTO) was founded, there have been significant changes to the global trading environment. The trade-related (aspects of) intellectual property rights agreement (TRIPS) was negotiated as a result of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), and the pharmaceutical industry was a major proponent of including IP issues in the GATT framework. After India signed the TRIPS agreement on April 15, 1994, it was required to follow the GATT's guidelines.

India must abide by the fundamental principles concerning patents and the pharmaceutical industry that are delineated in the TRIPS Agreement. Both pharmaceutical items and procedural developments must now be covered under the nation's patent legislation. A pharmaceutical product or technique that satisfies certain requirements can be granted a patent, which must last for at least 20 years.[10]

The first step in the Indian patent registration process is to conduct a patent search before the patent application is formally filed. The main need for Indian patent registration is novelty, which can be established through patent searches. Once the invention's novelty and originality have been established, an application for a patent may be filed with the Indian Patent Office at any of its regional offices, which are located in Delhi, Mumbai, Chennai, and Kolkata.

[8] The Patents (Amendment) Act, 2005(Act 15 of 2005), s.92A.
[9] Katherine Connor Linton, Nicholas Corrado, "A "Calibrated Approach": Pharmaceutical FDI and the Evolution of Indian Patent Law" 1 Journal of International Commerce and Economics 2-3(2007).
[10] Business Briefing: Pharmatech, "Patents and the Indian Pharmaceutical Industry"44(2002).

Applications for patents might be filed in full or in part. In the course of the patent application procedure, these two filings have different functions. A provisional patent filing helps obtain an early filing date and creates patent protection for a product that has not yet been developed. Following the submission of a provisional application, the patent is still listed as "Pending." There is an additional 12-month period to further develop the invention prior to the filing of a final patent application.

A complete patent filing, on the other hand, contains all of the applicant's claims, an in-depth description of the developed invention, and any diagrams that are required to support them. The goal is to effectively register the innovation with the Patent Office by disclosing the concept in full and in detail.[11]

Requirements for Patent Registration in India

To be eligible for patent registration in India, an innovation needs to meet certain standards. Before beginning the patent registration process, it is imperative to understand the qualifying requirements. The primary criteria used in India to determine eligibility for patent registration are as follows:

- **Novelty:** Once the invention's novelty and originality have been established, an application for a patent may be filed with the Indian Patent Office at any of its regional offices, which are located in Delhi, Mumbai, Chennai, and Kolkata.

- **Inventive step:** An invention needs to be novel or non-obvious, meaning that a person with the necessary technological expertise should not be able to easily identify it. Technology or creative ideas that cannot be easily inferred or obvious from prior art or current understanding must be the focus of the invention.
- **Industrial applicability:** For an invention to be deemed industrially applicable, it must be able to be produced or employed in an industry. It should have practical applications in many different technology fields and be beneficial in the actual world.
- **Exclusions:** Not every invention qualifies for the registration of patents. Patent protection does not apply to certain topics, such as inventions that violate order, morality, or public health. Moreover, patentability does not apply to discoveries,

[11] Step by Step Procedure For Patent Registration in India, available at Step by Step Procedure For Patent registration in India (setindiabiz.com)(last visited on January 6, 2024).

mathematical techniques, scientific ideas, artistic creations, or computer programs in and of themselves.

- **Ownership:** The person making the patent registration request must be the true, original inventor or the inventor's assignee. The patent application must list joint inventors as co-inventors.[12]

However, Section 3(d) of The Patents (Amendment) Act, 2005 specifies an additional requirement that must be met before a pharmaceutical patent can be awarded. This requirement necessitates a higher level of efficacy in the novel version of the known drug.

Compulsory licensing:

A compulsory license is a kind of statutory license that the Controller of Patents may grant to a third party under certain situations. Compulsory licenses are, in the context of the patent system, agreements between unwilling sellers and willing buyers that are enforced by the government. The government can grant a compulsory license, allowing third parties to manufacture a patented good or use a patented method even in the absence of the patent owner's approval. The grounds for granting a compulsory license are outlined in Section 84 of the Patents Act of 1970 and include the following:

(i) Regarding the patented invention, the public's anticipated needs have not been met;
(ii) The public is not given reasonable access to the patented invention; or
(iii) Within the borders of India, the patented invention is neither used nor implemented. However, the granting of a compulsory license can only take place after a three-year period from the patent grant date. [13]

Stepwise procedure for grant of patent in India

Patent search:

A worldwide patent search is the first step in the Indian patent filing procedure, and it determines whether an invention is novel. In the event that an invention is found to be in the prior art or to be strikingly similar to the prior art, the Indian Patent Office has the right to

[12] Rajnish Kumar Rai, "Patentable subject matter requirements: an evaluation of proposed exclusions to India's patent law in light of India's obligations under the trips agreement and options for India" 8 Chicago-Kent Journal of Intellectual Property 49-54(2008).
[13] Vipin Mathur, "Patenting of Pharmaceuticals: An Indian Perspective" 4 International Journal of Drug Development & Research 32(2012).

dispute its novelty and object to an application. Doing prior patent searches is essential to ascertain the possibility that the innovation office will accept your idea.

Drafting patent specification:

The invention's specification, which may or may not contain the inventor's claims, is written in a techno-legal language after comprehensive worldwide searches. While the complete specification includes elements with particular claims, the preliminary specification only includes elements without. The invention's application domain is defined in this document, which also includes a comprehensive explanation and real-world examples. It also offers recommendations for optimal procedures and is easy to use for those with the necessary technical know-how. The patent is given legal protection once the specification is finished and drafted with the inventor's claim.

Patent application filing:

After the patent specification is finished being written, the Indian patent application procedure can start. As previously stated, based on the submitted written specifications, patent applications may be of either full or provisional type. Once prepared, the provisional specification is filed using Form 2, and the patent application is filed using Form 1, in accordance with the guidelines outlined in the Indian Patent Act. It is crucial to remember that within a year of the provisional specification's filing date, the inventor's claims in the specification for a provisional patent must be included in the final specification.

Patent publication for public opposition:

When the application process is finished, the patent is opened for public examination and viewing eighteen months following the date of priority or filing, whichever occurs first. It is then published in an official journal. Now, anyone can validly object to the patent on behalf of the entire public.

Requesting patent examination:

An application for a patent is only reviewed once an examination request has been submitted. Within 48 months of the priority date or the patent filing date, this request must be submitted. A patent examiner then assesses the application and provides an examination report that includes the examiner's objections. Within a year after the examination report's release, a

response must be sent. The examiner may call the applicant or their agent for a show-cause hearing to answer the objections made if it is thought suitable.

Approval of a patent:

The patent application is prepared for the grant of patent registration once the applicant has addressed each of the objections listed in the examination report and the examiner is satisfied with the responses provided. This completes the procedure of registering a patent. The examiner may decide to reject the patent application if they are dissatisfied with the applicant's response and any supporting documentation. In this case, the applicant will have to repeat the entire Indian patent procedure in order to receive patent protection.[14]

Grant of Pharmaceutical Patents and The Impact Of Trips Agreement

Since the 1990s, the Indian pharmaceutical sector has become self-sufficient in terms of production and has grown to become one of the global leaders in the export of pharmaceuticals. The industry's success can be credited to its ability to conduct research and development (R&D) and manufacture generic pharmaceuticals that have been enhanced within the framework of patent protection provided by the Patent Act of 1970. This legislation aided domestic R&D by recognizing process patents rather than product patents. Among developing nations, India had a distinct position due to its robust generic pharmaceutical sector, which enabled it to offer medications at some of the lowest global prices. The growth of domestic pharmaceutical R&D in India underwent a sea change at that time. For goods that were patented in another nation, the act promoted reverse engineering and the creation of substitute processes.

India joined the World Trade Organization (WTO) in 1995 and was obliged to abide by the TRIPS Agreement's terms as a signatory. The TRIPS agreement was formally negotiated in April 1994 after being discussed during the Uruguay Round of trade negotiations. Since coming into force on January 1, 1995, the TRIPS Agreement has grown to be a major international framework for the protection of intellectual property. The institutional elements that had facilitated the industry's expansion were altered by the 1970 Patent Act Amendment. It was believed that the development of the Indian pharmaceutical industry would be impeded by the establishment of pharmaceutical product patents. India amended the Patent Act in March 2005 to conform to the TRIPS agreement of the World Trade Organization (WTO), which established

[14] Patent Registration Process In India: A Comprehensive Guide To Filing And Prosecuting Patent Applications, available at Patent Registration Process In India: A Comprehensive Guide To Filing And Prosecuting Patent Applications - Patent - India (mondaq.com)(last visited on January 6, 2024).

global minimum standards for intellectual property protection. Since then, there have been numerous discussions over the effect of the TRIPS Agreement on pharmaceutical patenting in India. Critics voice worries about public health, accessibility, and affordability of medicine, while supporters contend that it has improved intellectual property protection and encouraged innovation. [15]

India had a long-standing system of process patents, which allowed for the creation of generic medications without the requirement for patents on the end products. The key concern of the amendment was the reinstatement of the product patent regime and the restrictions this modification placed on its ability to develop technology via reverse engineering.

The country's Patents Act had to undergo three sets of amendments as part of India's consonance to fully implement the TRIPS Agreement. While developing nations generally had until January 1, 2000, developing countries such as India, whose process patent regime covered pharmaceuticals and agricultural chemicals, were granted an extension to transition before they had to introduce product patents on January 1, 2005.[16]

The first amendment to the Patents Act of 1970[17] Allowed for the filing of product patent applications by introducing provisions for "transitional arrangements" through Section 5(2). Exclusive Marketing Rights (EMRs) were made easier to issue concurrently with Chapter IVA. Following that, on January 1, 2000, a Second Amendment[18] was required in order to bring the Patents Act into conformity with the substantive standards specified in the TRIPS Agreement, with the exception of sections concerning the application of product patents. A third amendment was required by January 1, 2005, in order to comply with TRIPS entirely. Its goal was to establish a system of product patents in sectors that were previously under the purview of process patents, especially in industries such as medicines. Important issues like objections to patent grants were also covered by the Third Amendment.[19]

It should be emphasized that two of India's three Patents Act amendments were implemented in the context of significant global development. Growing concerns in developing nations about access to affordable medications sparked extensive confabulation among WTO members. This resulted in the Ministerial Declaration, which was signed in the 2001 Doha Ministerial

[15] Atsuko Kamiike, "The TRIPS Agreement and the Pharmaceutical Industry in India", 32(1) Journal of Interdisciplinary Economics 96-100(2019).
[16] TRIPS Agreement, 1994, art. 65.
[17] The Patents (Amendment) Act, 1999(Act 17 of 1999).
[18] The Patents (Amendment) Act, 2002(Act 38 of 2002)
[19] The Patent (Amendment) Act, 2005 (Act 15 of 2005).

Conference on the TRIPS Agreement and Public Health. The Doha Declaration declared unambiguously at the outset "that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health"[20] The Ministers further emphasized “that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all”. It was emphasized that the TRIPS Agreement's flexibility provisions may be fully utilized by World Trade Organization (WTO) members to suit their own specific needs.

The Doha Declaration highlighted two critical issues. The first emphasizes the significance of interpreting TRIPS Agreement clauses in accordance with its underlying objectives and principles. According to Article 7[21] of the TRIPS Agreement, intellectual property rights protection and enforcement should promote social and economic well-being while maintaining a balance of rights and responsibilities. Furthermore, Article 8[22] requires WTO Members to take appropriate precautions to protect public health and nutrition when developing or updating intellectual property rules and regulations. Essentially, the Doha Declaration highlights the importance of viewing TRIPS rules through the lens of promoting social well-being, economic balance, and public health preservation.

The second major point addressed by the Doha Declaration is compulsory licensing, a critical aspect that could have a significant impact on the trajectory of the Indian pharmaceutical industry. Compulsory licenses are widely acknowledged to play an important role in minimizing potential patent abuse. This scenario occurs when a patent holder uses their statutory rights to prevent competitors from entering the market. The Paris Convention provides some context for this matter. The Stockholm Act of the Paris Convention makes it clear in Article 5A.[23] That a patent's "insufficient working" or "failure to work" is an "abuse" of rights. The patent issuing authority was given the authority to grant a license to anyone prepared to "work" the patent if the patent rights were abused due to non-working or inadequate functioning. When considering it from a more practical standpoint, this means of compulsory licensing gives potential technology users—especially those in developing nations—the chance to obtain access to private technologies. Since generic companies in the Indian pharmaceutical

[20] Doha Declaration, 2001.
[21] TRIPS Agreement, 1994, art. 7.
[22] TRIPS Agreement, 1994, art. 8.
[23] Paris Convention, art. 5A.

business are no longer able to achieve their technology requirements by using reverse engineering, the compulsory licensing system could be very helpful to them.

According to the Patents Act[24], the opportunity to seek a compulsory license arises three years after the patent is awarded, unless exceptional circumstances, such as a national or acute emergency, require an earlier issue. The prerequisites for obtaining a compulsory license stem from three main factors: (1) the patent innovation has not sufficiently satisfied the reasonable needs of the public; (2) the patent innovation is not reasonably available to the public at a reasonable cost; and (3) the patent innovation is not actively being used within the territory of India.

Furthermore, in accordance with the TRIPS Agreement, India's pharmaceutical business has become globalized. The pharmaceutical industry's global value chain (GVC) has been restructured, including expansion into new markets like as India. In the aftermath of the TRIPS era, Indian pharmaceutical companies have actively participated in the pharmaceutical GVC by forming strategic partnerships and alliances with overseas pharmaceutical corporations. This evolution indicates a dynamic shift in the industry's landscape, as Indian companies become more integrated into the global pharmaceutical supply chain. GVC participation promotes technology transfer and upgrading. Indian pharmaceutical companies are modernizing while functioning in the GVC by implementing cutting-edge technologies. Furthermore, Indian pharmaceutical businesses are expanding their R&D investments to drive product innovation. The pharmaceutical industry prioritizes research and development. Within the TRIPS Agreement's patent system, the pharmaceutical sector's long-term growth is dependent on ongoing research and development (R&D) initiatives targeted at developing new treatments and advancing technologies. To remain competitive in the global pharmaceutical market, Indian businesses have expanded their R&D investments. This strategic shift has resulted in an increased emphasis on R&D within these organizations, indicating a movement toward more research-focused projects. Furthermore, the TRIPS Agreement has had a significant impact on the Indian pharmaceutical industry's patenting attempts. The need to comply with worldwide patent standards has led businesses to actively pursue and obtain patents for their discoveries. This increased patenting activity not only demonstrates a dedication to intellectual property protection but also positions Indian pharmaceutical companies as active contributors to global innovation within the TRIPS Agreement. Medical enterprises in India can now file patent

[24] The Patent Act, 1970 (Act 39 of 1970), s. 92A.

applications for their medicinal products, techniques, and formulations. As a result, patent filings by Indian and multinational pharmaceutical businesses in India have increased significantly.

Implications of Pharmaceutical Patents on The Patients and The Health Care System of The Country

In India, a significant proportion of the populace lives in poverty, and most people pay for their own medical treatment. This sobering fact highlights a severe health crisis marked by shortcomings in the delivery of healthcare and issues with the availability, price, and accessibility of medications in the nation. The Indian pharmaceutical industry has come a long way from being an import-dependent business in the 1950s, and it is now well-recognized as an affordable manufacturer of high-quality pharmaceutical products. The industry's yearly export revenue is currently in the billions, indicating a noteworthy rise in the international arena. However major ramifications and difficulties have emerged since the country's new patent policy was put into force, especially for patients and the country's healthcare system. The transition to a system of product patents has brought forth complications that need to be carefully considered in light of healthcare accessibility, affordability, and public health in general.

Inadvertently giving innovators patent protection has unintentionally given them the ability to set monopoly prices, leading to prolonged monopolies in the pharmaceutical industry. Due to this dynamic, necessary medications that are still covered by patents are now out of reach for a common man monetarily. While there is no denying that pharmaceutical innovations have improved and saved lives all over the world, there is strong evidence to suggest that pharmaceutical companies have largely neglected the development of drugs that meet the needs of smaller populations and the economically disadvantaged because they are attracted to the large returns associated with patented drugs. Moreover, it is noted that poor countries frequently encounter difficulties in utilizing flexibility included in their national legislation because of pressure from industrialized nations, even when these provisions are present. Thus, it would seem that the current global patent law framework is biased against the needs of developing nations to protect the right to health for all of their residents, especially the less fortunate. This points out an urgent issue: the healthcare needs of people worldwide, particularly those in less developed areas, are not being sufficiently met by the current system.

In terms of novel medication availability, the adoption of the TRIPS agreement has presented benefits and obstacles to less developed, developing, and third-world nations. In positive terms, the TRIPS agreement has encouraged the creation of novel medications that otherwise might not have been explored. Product patents are seen favourably since they give the developed world access to the newest medical advancements, which in turn encourages the developed world to export these innovations to nations such as India. The accessibility drawback, though, becomes apparent. These countries can now no longer take advantage of the cost advantages provided by generic medications, even though they can still afford the high monopoly pricing linked to strong patents. The economically disadvantaged are disproportionately affected by the expansion of strong intellectual property rights into less developed nations, made possible by TRIPS.

The pharmaceutical sector and trade negotiators must not lose sight of the core goal of medication innovation: to save lives. Profit should be considered a means to an end, not an end. We may aim to effectively protect the safety and well-being of the world's people in the twenty-first century and beyond by being committed to this ideal and acquiring a greater awareness of the modern global health scenario. The primary focus should be on advancing medical discoveries that benefit society and save lives.

In India, achieving access to healthcare faces numerous impediments, necessitating the creation of constitutional provisions and a slew of judicial rulings to uphold this necessity. Despite the judiciary's repeated rulings on various aspects of healthcare access, the failure lies in the implementation of legislative measures. There is a significant administrative void that needs to be addressed. Examining the constitutional framework, the functions of legislation, administrative agencies, and the courts, is critical to ensuring effective healthcare access. Comprehensive assessment and coordinated efforts across all sectors are required to close existing gaps and improve the country's access to healthcare services.

Conclusion

In 2005, India made significant changes to its patent regime for pharmaceuticals. Since then, the country has granted several patents to both domestic and international corporations. There were widespread apprehensions across the country that the new patent system would result in significant price increases and limit access to affordable drugs in the country. Unquestionably, the consequences of the new system have included both adverse and positive aspects, as detailed in the paper. The TRIPS Agreement, with its flexible procedures such as compulsory licensing,

parallel importation, and patent opposition, has attempted to strike a balance between ensuring access to medicines and treatments and protecting intellectual property.

The TRIPS Agreement has caused a global shift in the pharmaceutical sector, resulting in a reorganization of the global value chain (GVC) and its expansion into developing countries such as India. This arrangement has created new growth opportunities for Indian pharmaceutical companies, and their participation in the GVC has facilitated technological advancements and technology transfer. Indian pharmaceutical companies are strengthening their position in the GVC by using modern technologies and utilizing strong research and development capabilities. This upgrading procedure has been critical in accelerating the growth and advancement of the Indian pharmaceutical business in the post-TRIPS era.

The importance of international human rights is paramount in an era where health care transcends national borders. To ensure effective engagement, every country should take an active role in international affairs. The ultimate goal of medication innovation is to save lives, and this is something that both the pharmaceutical industry and trade negotiators need to be mindful of. In a sector committed to saving lives, profit should always be a means to this vital goal rather than the end in and of itself.