ISSN No:-2456-2165

Professional Skill Development Activity
Delhi Metropolitan Education
(Affiliated To GGSIPU)

Pharmaceutical Patenting in India- Assessing Challenges to Public Access to Essential Medicine

CHAYAN SHREE UPADHYAY, LAVANYA BHAGRA
ENROLLMENT NO- 05351103819
BALLB- 4A

Abstract:- Pharmaceutical patenting plays a critical role in promoting innovation and ensuring the availability of effective and affordable medicines. However, in developing countries like India, the issue of public access to healthcare becomes a significant concern when considering the implications of pharmaceutical patenting. This abstract highlights the challenges faced by Indiain balancing the protection of intellectual property rights and the need to provide accessible healthcare to its population. India, being one of the largest producers of generic medicines, has a long history of implementing a robust intellectual property regime that balances patent protection with public health interests. However, the introduction of product patents in India in 2005, in compliance with the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, posed new challenges. The pharmaceutical patenting landscape in India has seen an increase in the number of patents filed by multinational pharmaceutical companies for innovative drugs. While patent protection encourages research and development, it also creates barriers to access for essential medicines, especially for underprivileged populations. The high cost of patented medicines often places them out of reach for many individuals, exacerbating health inequalities and impeding progress towards universal healthcare.

Furthermore, the pharmaceutical patenting system faces additional complexities, including evergreening strategies, where companies seek to extend patent protection by making minor modifications to existing drugs. This practice can delay the entry of generic versions into the market, hindering competition and affordable access to life-saving medications. The Indian government has taken steps to address these challenges through legal provisions, such as compulsory licensing, which allows the production of generic versions of patented drugs in the interest of public health. Additionally, the government encourages domestic manufacturing and promotes research and development in the pharmaceutical sector to foster innovation and reduce dependency on imported medicines. To enhance public access to healthcare, various stakeholders, including the government, pharmaceutical industry, and civil society, need tocollaborate and devise strategies that strike a balance between intellectual property protection and affordable healthcare.

I. INTRODUCTION

"Access to affordable and life-saving medicines should not be compromised by the complexitiesof pharmaceutical patenting. We must find a balance that protects intellectual property rights while ensuring public health for all."

Pharmaceutical patenting is a crucial aspect of the global healthcare landscape, providing incentives for innovation and enabling the development of life-saving medications. However, theinterplay between pharmaceutical patenting and public access to health poses a significant challenge in countries like India. This introduction provides an overview of the issue and sets thecontext for understanding the problem of public access to healthcare in relation to pharmaceutical patenting in India. India, with its large population and diverse healthcare needs, faces unique challenges in ensuring affordable and accessible healthcare for all. The introductionof product patents in India in 2005, as mandated by the TRIPS agreement, marked a turning point in the country's pharmaceutical industry. While the introduction of patents aimed to encourage innovation and attract foreign investment, it also raised concerns about the

ISSN No:-2456-2165

affordability and availability of essential medicines. India has long been a model for developing countries, adapting drug laws to meet domestic health needs, placing greater emphasis on the needs of the general public, and thereby responding to their growth. Most of India's population lives below the poverty line, and most of the medical costs have to be paid at their own expense, due to lack of medical care, accessibility, affordability and availability of medicines. Clarifiesthat is facing a serious health crisis. Indian Patent Law provides for exclusivity under Section 3 (d). "By protecting access to medicines for the poor, the Agreement strikes a good balance between its mission and the Agreement on Trade-related Aspects of International Trade (TRIPS)." TRIPS launched. Since then, this has definitely been a remarkable change of particular concern today is the Indian drug patent system. Indian pharmaceutical companies and the Indian market are major suppliers of low-cost medicines such as generics that are essential for public health. India is a member of the 2001 TRIPS and Doha Declaration on Public Health and has had a global impact on access to medicines over the last 1000 years. The export-oriented pharmaceutical industry, with its ever-increasing commitment to civil society, is essential to its development. Global Access Campaign for Pharmaceuticals has been a regional leader since its inception in India. The Indian industry has formed the backbone of the campaign by demonstrating the potential for the creation of alternative pharmaceutical industries. Accordingto recent Indian patent law decisions, including the Novartis Supreme Court's decision, India continues to prioritize public health when deciding whether to grant drug patents. Therefore, the pharmaceutical patent system limits the competition for generic drugs. As a result, prices are rising andaccess to medicines in developing countries is becoming more difficult.

II. LITERATURE REVIEW

"PHARMACEUTICAL PATENTING IN INDIA: PROBLEM OF PUBLIC ACCESS TO HEALTH" is an article by Shereen Saman Review and analysis of patent rules for pharmaceutical products in India is included in this article together with issues of public health access.

"PHARMACEUTICAL PATENTS A THREAT TO INDIA'S DRUG INDUSTRY? –FOOD AND DRUGS LAW – INDIA (2018)" is an article by Shubhra Khanna's research, the TRIPS agreement has attempted to strike a balance between protecting intellectual property rights and ensuring that people have access to medicines and treatment through its flexible procedures such as parallel improvisation, compulsory licensing, and patent opposition.

III. STATEMENT OF PROBLEM

The high cost of patented drugs creates barriers that hinder access to healthcare, particularly for economically disadvantaged individuals. Additionally, the practice of evergreening, which extends patent protection through minor modifications, further limits the availability of affordable generic alternatives. This problem exacerbates health inequalities and hampers progress towards achieving universal health coverage in India.

IV. HYPOTHESIS

The problem of public access to health in India, particularly in relation to pharmaceutical patenting, could be mitigated through the implementation of stronger regulatory measures and increased government investment in healthcare infrastructure.

V. RESEARCH QUESTIONS

- How has the Indian pharmaceutical patent system affected the general public's right to health?
- What has changed in the judicial perspective and the trend related pharmaceutical patents?
- How can India's demand for drugs and pharmaceutical innovations coexist in harmony?
- What effect do patents have on India's economic development?
- What regulations govern the patenting of vaccinations for diseases that are endemic over the world? Suggestions for the best course of action under these momentous circumstances.

VI. RESEARCH METHODOLOGY

The research work is conducted through Doctrinal research by relying upon secondary sources.

VII. INTELLECTUAL PROPERTY RIGHTS (IPR) IN INDIA: OVERVIEW

Intellectual Property Rights (IPR) in India refers to the legal rights granted to individuals or entities for their intellectual creations or inventions. These rights aim to protect and encourage innovation, creativity, and investment in various fields such as inventions, literary and artistic works, designs, and trademarks. Here's an overview of IPR in India:

- **Patents:** Patents give inventors exclusive rights to their inventions, enabling them to stop others from manufacturing, using, or commercializing their invention without their permission. In India, patents are governed by the Patents Act, 1970, and are granted by the Indian Patent Office. The term of a patent is 20 years from the dateS of filing.
- **Trademarks:** Trademarks safeguard distinguishing indicators that set one company's products and services apart from those of competitors, such as logos, names, and symbols.. The Trademarks Act, 1999, governs trademarks in India. Trademark registration provides exclusive rights to the owner and is valid for a period of ten years, renewable indefinitely.
- ✓ **Copyrights:** Copyright protects original literary, artistic, musical, or dramatic works. It grants exclusive rights to authors or creators, allowing them to reproduce, distribute, display, or perform their work. Copyrights in India are governed by the Copyright Act, 1957. The duration of copyright protection varies depending on the type of work but generally extends for the lifetime of the author plus 60 years.

- ✓ **Designs:** Designs refer to a product's outside appearance, which may include its form, arrangement, pattern, or adornment. Design protection stops others from copying the design without authorization. Design registration in India is governed by the Designs Act, 2000, and offers ten years of protection that may be extended by a further five years..
- ✓ **Geographical Indications (GIs):** Geographical indicators describe products with characteristics or a track record peculiar to their place of origin and origination. Darjeeling tea and Kanchipuram silk are two examples. The Geographical Indications of Goods (Registration and Protection) Act, 1999 protects geographical indications in India.
- ✓ **Trade Secrets:** Trade secrets are priceless pieces of sensitive information that provide companies a competitive edge. Although there is no specific legislation governing trade secrets in India, they are protected under common law principles and contractual agreements.

India is a member of several international treaties and organizations related to intellectual property, such as the World Intellectual Property Organization (WIPO)[1] and have made efforts toalign its laws with international standards. The government has taken steps to streamline the registration process, enhance enforcement mechanisms, and promote awareness about IPR to foster innovation and protect the rights of creators and inventors in the country.

VIII. PHARMACEUTICAL PATENTING: MEANING

"At the point when a pharmaceutical company initially builds up a medication to be utilized for adisease condition, it is at first traded under a brand name by which the clinicians can endorse the medicines for use by patients. The drug is secured under the protection of a patent, which impliesthat only the pharmaceutical company that holds the patent is permitted to produce, showcase the medication, and, in the long run, make benefit from it. The patent time-period for the patent on a drug after getting approval is usually around 7-12 years. It is because companies apply for patent sometime before the clinical trial to survey a medicine's wellbeing. Once the patent has expired, the drug can be manufactured and sold by other companies. At this point, the drug is referred to as a generic drug."

IX. PATENT LAWS AND PHARMACEUTICAL PATENTING IN INDIA

"The Indian pharmaceutical industry has a strong generic base with almost 60,000 generic brands in 60 therapeutic categories in the market which was nurtured by the then legal system concerning patent. The growth of the domestic pharmaceutical industry creates one of the success legends of the Indian economy. From the time being an import-dependent enterprise in the era of the 1950s, the Indian pharmaceutical industry has achieved global recognition in today time, as a cost-effective generator of a high-standard and high-quality pharmaceutical products. Its yearly exportation turnover exceeds $1.5 billion. This was achievable because, at that time, noproduct patent system for drugs and pharmaceuticals existed."

Patent laws in India govern the protection and enforcement of intellectual property rights, including pharmaceutical patenting. India had a product patent regime for all inventions under the Patents and Designs Act 1911. The key legislation governing patents in India is the Patents Act, 1970, which has undergone amendments to align with international standards and obligations, particularly under the Trade-Related Aspects of Intellectual Property Rights (TRIPS)agreement. The Indian pharmaceutical industry was significantly impacted by the lack of safeguards for product intellectual property in the pharmaceutical and agrochemical industries, which led to the creation of substantial knowledge in the opposite direction science and technology of drugs that are patentable as goods all through the industrialized world but unprotect able in India. As a result, the Indian pharmaceutical business quickly expanded by creating less expensive versions of certain medications that had domestic patents. When those domestic patents had expired, the company then aggressively entered the global market with generic medications. The Patents Act also includes a number of measures to stop the infringement of patent rights and to improve access to medicines.

Additionally, there are measures for compulsory licensing in the Patents Act. When three have been reached anyone who is interested in using the invention that has been patented may submit an application for an invention-related obligatory licence as of the patent's closing date. When the patent controller is convinced that the public's reasonable demands regarding the patented invention were not fulfilled or that the patented invention is not yet accessible to the public at large, may the patent controller order the owner of the patent to issue such a licence under any conditions that may be considered appropriate a reasonable price.[2]

"Section 3(d) of the Patents Act, 1970 says that the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of aknown process, machine or apparatus unless such known process results in a new product or employs at least one new reactant, is not patentable."

The provision under section 3(d) According to the WHO Public Health Innovation and Intellectual Property Rights Report, 2006, nations may pass laws and regulations establishing standards for patent applications that would make it more difficult to obtain ever-greening patents. The Novartis case's Indian patent law judgment signifies an important victory for communities' possession of affordable medicines in developing countries and has an impact on the poor's ability to get medications. If Novartis had won the lawsuit, medication registering may have gained wider acceptance in the nation of India, limiting generic competition and obstructingaccess to affordable medicines in underdeveloped countries. Additionally, the practice is unlawful because it will allow multinational corporations (MNCs) in the pharmaceutical industryto reduce rivalry with generic producers thus pay.

ISSN No:-2456-2165

X. CASE LAW

The most recent case, ***Novartis AG v Union of India*** decided by Supreme Court of India in 2013also known as the Novartis case, was a significant intellectual property case that reached theSupreme Court of India. The case dealt with the patentability of Novartis' anticancer drug, Glivec (also known as Gleevec), under Indian patent law. "Where the case began in the year 1997 with patent application filed by the petitioner before Chennai patent office related to drug name Glivec, which was slightly a different version of their 1993 patent for Anti leukaemia drug. In this case the Assistant Controller of Patent and design, Chennai Patent Office rejected the application under section 3(d) of the Indian patent act 1970. Consequently, the petitioner challenged the constitutionality of section 3(d) before High Court at Madras."

The applicant in the present appeal contented on two issues:

- Section 3(d) is unlawful since it contravenes the TRIPS agreement's provisions..
- The Indian Patent Act gives the Controller unrestricted power and lacks a definition for the word "efficacy." It is therefore arbitrary, irrational, and ambiguous.

In response to the above contention the court held that:

- For violations of the Agreement, the WTO's dispute agreement offers the sole remedy and a thorough dispute process. In a similar disagreement, the High Court determined that external lawprevails after considering the conflict between transnational law and external law. Transnational covenants are also not directly applicable in India. enforceable.[3]
- "The court also rejected the alternate contention that the provision is furnishing unguided power to the patent regulator being arbitrary on the base of the term' efficacy' was undetermined and thus the court observed that "Efficacy means the ability to produce a desired or intended result. Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of medicine that claims to cure a disease, the test of efficacy can only be 'therapeutic efficacy."

"Therefore, it is found that the Novartis‟ patent application for the beta-crystalline form of Imatinib Mesylate did not pass the test of section 3(d) as it did not have any enhanced therapeutic efficacy. The Supreme Court thereby upheld the observation of the High Court and Indian Patent office and rejected the patent application filed by the petitioner."

XI. HOW PHARMACEUTICAL PATENTING IS CAUSING PROBLEMS INPUBLIC ACCESS TO HEALTH?

Regarding its effect on Indian medical assiduity and availability to necessary medications both inside and outside the nation, there are varying opinions. India has a significant number of pharmaceutical businesses and is rated fourth in terms of product quantity. Although pharmaceutical medicine patents are still a crucial component in the procedure of invention, the patent system in its entirety can be confusing to those who are not familiar with it. For example, pharmaceutical companies often overcharge for patented drugs and abuse the monopoly of patents. The availability of medicines has decreased as a result of product patents. In India, manygeneric medications, including vaccinations, are being patented, making it difficult to produce life-saving medications.

- **High Drug Prices**: Pharmaceutical patents grant exclusive rights to the patent holder, allowing them to set high prices for their patented drugs. This can make essential medications unaffordable for many people, particularly in low-income countries or for those without adequate health insurance coverage. High drug prices can restrict access to life-saving treatments and contribute to health inequalities.
- **Lack of Generic Competition:** Patents provide a monopoly to the patent holder, preventing the entry of generic versions of the same drug into the market for the duration of the patent. Generic competition plays a crucial role in reducing drug prices and increasing access to affordable medicines. When pharmaceutical patents block generic competition, it can impede access to more affordable options for patients.
- **Limited Availability in Developing Countries:** Pharmaceutical companies may choose not to launch or market their patented drugs in certain developing countries due to perceived low profitability or market size. This limits the availability of essential medications in those regions and hinders access to necessary treatments.
- **Delayed Access to New Medicines:** Patents can create barriers that delay access to new medicines. Patent holders may engage in strategic patenting practices, such as evergreening, where they make minor modifications to existing drugs to extend their patent exclusivity. These practices can delay the entry of generic versions and limit timely access to affordable alternatives.
- **Impact on Health Budgets:** High drug prices resulting from pharmaceutical patents can place a significant burden on healthcare budgets, especially in resource-constrained settings. Limited funds may force governments to prioritize certain treatments, potentially leaving some patients without access to essential medicines.

Efforts to balance patent protection and public health are ongoing. Initiatives such as compulsorylicensing, which allow governments to grant licenses to produce generic versions of patented drugs without the patent holder's consent, have been utilized to improve access to affordable medications. Compulsory licensing reduces prices to consumers by creating competition in the market for the patented good.[4] Additionally, international agreements like the World Trade Organization's Agreement on Trade-Related

Aspects of Intellectual Property Rights (TRIPS) have provisions to support access to medicines in developing countries.

Overall, addressing the challenges arising from pharmaceutical patenting requires a careful balance between incentivizing innovation and ensuring equitable access to affordable medicines for the public's health benefit.

XII. CONCLUSION

On one hand, pharmaceutical patenting encourages innovation by providing exclusive rights to inventors, which incentivizes the development of new drugs and treatments. This can lead to advancements in healthcare and improved treatment options for patients. Patent protection also enables companies to recoup their research and development costs, which can be substantial, and encourages further investment in the pharmaceutical industry.

However, there are concerns regarding public access to affordable medicines, especially in developing countries like India. Patent monopolies can lead to high drug prices, limiting access to life-saving medications for those who cannot afford them. This issue is particularly significant in the context of public health, where access to affordable drugs is crucial for the well-being of a large population. In conclusion, pharmaceutical patenting in India presents a complex issue with competing interests. While patent protection is essential for encouraging innovation and investment in the pharmaceutical industry, it must be balanced with the need to ensure public access to affordable medicines. India has taken steps to address this concern through provisions such as compulsory licensing and parallel imports. Continued efforts to strike the right balance between intellectual property rights and public health will be crucial to address the problem of public access to health in the context of pharmaceutical patenting.

REFERENCES

[1.] https://iprlawindia.org/wp-content/uploads/2021/04/Madhurima-Mohajon.pdf https://ijirt.org/master/publishedpaper/IJIRT157459_PAPER.pdf https://thelawbrigade.com/wp-content/uploads/2023/01/Shereen-Samant-JLSR.pdf
[2.] https://letslearnlaw.com/b/pharmaceutical-patenting-in-india-problem-of-public-access-to-health/ https://blog.iledu.in/pharmaceutical-patenting-in-india-problem-of-public-access-to-health/
[3.] https://iprlawindia.org/wp-content/uploads/2021/04/Madhurima-Mohajon.pdf https://www.investopedia.com/terms/i/intellectualproperty.asp https://www.labnews.co.uk
[4.] https://www.mondaq.com/india/patent/826478/a-study-on-novartis-ag-v-union-of-india https://www.lexology.com/
[5.] https://www.lexology.com/library/detail.aspx?g=3f92413f-107c-4886-aca7-24633a341e22 https://www.scconline.com/blog/post/2019/09/03/pharmaceutical-patents-and-healthcare-a-legal-conundrum/
[6.] https://lup.lub.lu.se/luur/download?func=downloadFile&recordOId=3955219&fileOId=3955220