PHARMACEUTICAL PATENTING IN INDIA-PROBLEM OF PUBLIC ACCESS TO HEALTH

- Aditya Prabu
VIT-AP School of Law

ABSTRACT

Intellectual property rights developed significantly in the post TRIPS agreement era. The World Intellectual Property Organization (WIPO) was looking into the intellectual property rights matters prior to the adoption of TRIPS agreement. TRIPS agreement has adopted multiple treaties on various aspects of IPR. The TRIPS agreement holds minimum standards for copyrights, patents, trademark, industrial design, layout design of integrated circuits and trade secrets. India has enacted legal practices(The Patent Act, 1970) to authorize intentional permitting exchange and rules for looking at application of drugs by utilizing TRIPS' agreement. To bring it in conformity with the provisions of TRIPS agreement the Patents Act was amended several times. Hence, the study made under this paper calculates the possibilites of implementing to increase access to affordable medicine with certain legal obligations in India.

I. INTRODUCTION

India has long been a leader in the developing world by modifying its pharmaceutical legislation to cater for local health demands, placing a greater priority on populace needs, and being in line with its growth. The majority of Indians live below the poverty line, and the bulk of medical costs must be covered out of pocket, demonstrating the country's acute health problem caused by inadequate healthcare, accessibility, affordability, and medicine availability. Section 3 of the Indian Patent Law grants exclusivity (d). The pact "strikes a fine balance between its mandate and the Agreements on Trade Related Aspects of International Trade (TRIPS) by ensuring access to pharmaceuticals for the poor". Since TRIPS was put into effect, this has unquestionably changed significantly. The Indian patent system for pharmaceuticals is a current issue of great importance. Generic medications, which are crucial to public health, are supplied in large part by Indian pharmaceutical businesses and the Indian market. India is a signatory to the 2001 Doha Declaration on TRIPS and Public Health, which has had an impact on the world's ability to acquire medications throughout the past millennium. For its development, the pharmaceutical sector needs to be export-focused and increasingly conscious of civil society. India has been a regional leader ever since the worldwide access to medicines campaign got its start there. The Indian industry supported the cause by proving that a different pharmaceutical business could be established. Recent decisions concerning Indian patent law, such as the Supreme Court's Novartis decision, indicate that India continues to give the public's health top priority when deciding whether to grant patents for pharmaceutical items. Therefore, the pharmaceutical patent system limits generic competition. As a result, drug costs increase and access to medications is restricted in developing nations.

II. PHARMACEUTICAL PATENTING MEANING

Any original invention may be protected by a patent, which also provides the requirement to sell, use, create, and/or manufacture the patented product. Drug or pharmaceutical patents have become increasingly

important as new and improved treatments are continuously introduced to the market and assist to produce sizable sums of money for commercial gain. Pharmaceutical care refers to the provision of medication as medical assistance as well as various patient care services designed to achieve goals such as patient care, symptom reduction or removal, or the sluggish progression of a condition. An individual who is currently licensed, registered, or otherwise permitted under the Act to administer medication or pharmaceuticals as part of their professional activity are referred to as a pharmaceutical Practitioner. Numerous phrases from Section 2(h) of the Act are utilized in Pharmacy Regulation 2015. The pharmaceutical industry is one area where innovation affects a very low-cost line of drug manufacturers. WHO targets research and development of a replacement drug and incurs significant costs in doing so, despite the lack of any assurance that their research product will survive various testing stages and be able to thrive commercially if released onto the market. The TRIPs Agreement requires the member states to protect biotech inventions, but it also gives them the option to exempt plants and animals from patentability. Protecting microorganisms and biological processes is necessary for production, though. Microorganisms are now permitted to be patented in India according to a 2002 modification to the Patents Act. To fulfill our commitments under the TRIPs Agreement, we made this change.

III. PHARMACY AND PATENT LAW IN INDIA AND PUBLIC HEALTH

According to Black's Law Dictionary, the word "health" a state of health or wellness in one's body, mind, or spirit. Not the same as "sanitation." The right to enjoy one's health, which is a subset of the right to personal security, is one of a person's fundamental rights. It is a law that outlines sanitary precautions and is intended to promote or protect community health. The officer is responsible for the social control and enforcement of health rules. Local laws regulate the authority and responsibilities of health officers. Public health is one of the goals of the state's police power and is defined as the general state of being healthy or hygienic among all people or within a community as a whole, as well as the absence of any broad or widespread sickness or cause of mortality. With approximately 60,000 generic brands available in the market across 60 categories, the Indian pharmacy sector has a solid foundation that has been cultivated by the country's regulatory framework around patents. As a result, the domestic pharmaceutical industry has expanded and become one of the success stories of the Indian economy. This was possible because there was no item patent system for medications and drugs at the time.

The Pharmacy Act of 1948 covers specific individuals when it comes to biotechnological work. In the areas of health care and environmental protection, biotechnology is crucial. The Pharmacy Council of India, with the assent of the Central Government, exercises powers and adopts regulations in accordance with Sections 10-18 of the Pharmacy Act, 1948. The Pharmacy Practice Regulation, 2015 under regulation 9, specifically addresses the dispensing and offering of medications. Each prescription that is given for dispensing must undergo a pharmaceutical evaluation by a registered pharmacist. For the purposes of the act, pharmaceutical evaluation is defined as the process by which a registered pharmacist uses his knowledge to analyze the efficacy, efficacy, safety, and reasonable use of prescribed medical treatments. The pharmacist should get involved in hospital-level, state-level, and federal formulary preparation in order to encourage the sensible use of medications. Registered pharmacists, who are also excellent citizens and have received specialized training, should offer advice on issues relating to public health. They should contribute to upholding the institution that serves humanity's best interests as well as enforcing local laws. They must cooperate with the authorities in particular when it comes to enforcing sanitary or public health rules and regulations.

They should contribute to upholding the institution that serves humanity's best interests as well as enforcing local laws. They will work closely with those who are knowledgeable on organising sanitary/public health rules and regulations in particular. Enrolled specialists will educate the general population about the isolation guidelines and precautions for the protection of the plague and communicable diseases, especially those working in the general public. Every time a case of a communicable disease comes to his attention, the registered drug specialist will notify the authorities in accordance with the laws, regulations, and instructions of the medical professionals. A licensed doctor won't abandon his duty in the event of an epidemic out of irrational fear of contracting the disease himself.

Following the TRIPs agreement, India was given a 5 year transition period in addition to 5 years to amend the current patent laws regarding pharmaceutical patent protection. After this, there were several amendments made in Indian Patent Laws;

1. The Patent (Amendment) Act, 1999 – Increased exclusive marketing rights in the transition period.
2. The Patents (Amendment) Act, 2002 – Widespread changes to keep up the TRIPs standards
3. The Patents (Amendments) Act, 2005 – Wide ranging improvement before the expiration of the transition period

The most recent modification, nevertheless, was made in 2005. The Indian Patent laws underwent considerable adjustments as a result. The Patents Act of 1970's Section 5, which stated that no patent shall be granted in respect of claims for substances intended for use, or capable of use, as food, medicine, or drug, or relating to materials prepared or produced by chemical processes, is eliminated by the amendment. This is the most significant change it brings about.

In the case of *Novartis AG and Ors v Union of India,* section 3(d) of the Indian Patent Act, 1970 was brought into the limelight. In this matter, the Appellant, Norvatis, applied to the Chennai Indian Patent Office for a permission of the patent of the medication name "Glivec," which is used to treat Chronic Myeloid Leukemia and Gastrointestinal Stromal Tumors, in conformity with the TRIPS agreement. The drug is not patentable under Section 3(d) of the Patent Act, 1970, according to the Madras Patent Office, which rejected his patent application in 2005. After that, the appellant filed two writ petitions with the Madras High Court pursuant to Article 226 of the Indian Constitution, which resulted in the matter being referred to the IPAB (Intellectual Property Appellant Tribunal) in 2007. The IPAB heard the petition and dismissed it in 2007 and hence, Novartis filed a Special Leave Petition before the Supreme Court of India but the Supreme Court rejected the approval.

IV. DRUG PATENTS AND GENERIC PHARMACEUTICAL DRUGS

When a pharmaceutical corporation develops a new drug, it is initially marketed under a brand name so that doctors can accept the drug for patient use. The pharmaceutical is protected by patent assurance, which means that the drug company holding the patent is allowed to manufacture, market, and ultimately profit from the treatment. It is claimed that after the patent expires, many businesses may develop and market the drug. A drug can be manufactured as a generic drug when the following applies; its patent has expired, the company that would manufactured the generic drug certifies that the patents held on the drug are either unenforceable, are invalid or would not be infringed upon and in the countries where the drug has no patent protection. However, the company holding the initial patent may extend it by developing a new formulation of the drug that is substantially different from the original component. Furthermore, unless the medication controllers identify faults and eliminate them, the new chemical might need to compete with the first traditional molecule that becomes available.

V. HOW PHARMACEUTICAL PATENTINGS CAUSING PROBLEMS IN PUBLIC ACCESS TO HEALTH?

Drug corporations frequently exploit the patent monopoly and charge exorbitant rates for copyrighted medications. The openness of drugs has decreased since the advent of item patents. Overall, the development of new pharmaceuticals necessitates substantial investments, extensive research, pricey clinical studies, and formal administrative approval processes. One of the incentives for creators of novel pharmaceuticals to invest the necessary funds into that research is the exclusive right provided by a patent. Numerous nonexclusive prescriptions, including vaccines, are protected in India, making it challenging for the business to create life-saving medications. The Indian government has adopted a number of steps to defend this situation, including parallel trade policies and mandatory licensing as alternatives that can assist non-industrial nation governments in making basic drugs more affordable for their citizens. By fostering competition in the market for the patented good, mandatory licensing

lowers prices for consumers. Exorbitant drug prices that prevent regular people from accessing medication go against the expectation of the government to preserve the health of its people. Particularly in a nation like India, where a sizable portion of the population lives below the poverty line and healthcare costs are high, it is obvious that there is a critical care emergency with inadequate access to healthcare, as well as a system that rewards innovators by granting them a patent monopoly. A patent has several advantages, not the least of which is the sole right to use it for commercial gain. Another idea is that improving the patent system would be a good step in the right direction. The issue of whether or not to grant patents for small improvements has come up recently. As a result, there will be less incentive to spend money on incremental innovation aimed at making improvements. Instead, money will be invested in R&D that the society needs by fostering an environment that is favorable for neglected medicines. Pharmaceutical corporations have a strong financial motive to test the limits of the protection system because of the lucrative nature of the industry. A patent is just another commercial instrument that these businesses can use to maximize shareholder returns. We can anticipate the originator sector working hard to increase the protective security of its protected invention resources in the best way it can, whether by innovation in technology, innovation in the application of legal processes, or both. An unfair method of patent infringement is the ever greening of patents, which encourage advancement in the pharmaceutical sector. It is merely introducing a minor modification or inconsequential improvement and then claiming a patent right for a further twenty years in order to obstruct generic competitors who are attempting to offer affordable, safe, and effective medications to the general public. If implemented or serves as an example for other developing nations, the rules construed in the Novartis case and the corresponding provision of Section 3(d) of the Patent Act may encourage businesses to spend more on innovation than on trying to patent little changes. Regardless of what it means for future innovation in the pharmaceutical industries, the Novartis decision will assist disadvantaged people around the world have better access to affordable pharmaceuticals.

VI. CONCLUSION

To push the theory to its logical conclusion, I would want to point out that the project's initial genesis was intended to call attention to the issue of public access to health care caused by pharmaceutical patenting in India. It is important to note that as technology and inventions advance, so do they. This rapid advancement can be considered as a law that increases efficiency by addressing a specific issue in a flexible way.

In the case of India, it encompasses both the demands of the regional pharmaceutical sector and the needs of numerous, expensive patient populations. The government should intervene and take proactive steps to ensure that everyone has access to affordable insurance plans with comprehensive health coverage. Additionally, the government should fund university-level research and development to create more affordable pharmaceuticals, and it should incentivize the public sector to conduct the necessary investigations. The nation must strike a meaningful balance between using the patenting law to encourage pharmaceutical companies to create novel treatments for diseases that are currently incurable and, on the other hand, the need for patients to profit from those treatments without bankrupting themselves or public finances.

VII. REFERENCES

1. Black’s Law Dictionary
2. *Novartis AG and Ors v Union of India (2013) 6 SCC 1*
3. Yamalapalli, G. *Pharmaceutical Patenting in India: Problem of Public Access to Health*
4. Surana D, 'Patent Landscaping' (*Livelaw.in*, 2021) <https://www.livelaw.in/law firms/articles/law-firms-patent-landscaping-167378> accessed 16 October 2021
5. Sampat B, Shadlen K, and Amin T, 'Challenges To India's Pharmaceutical Patent Laws' (2012) 337 Science