PHARMACEUTICAL PATENTING IN INDIA: ACCESS TO HEALTH PROBLEM

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ABSTRACT

This paper highlights and overview of and analysis of the patent laws in relation with the pharmaceuticals, the problems of public access to health in India. Moreover, patents have played a keen role in changing national and global innovation landscape. Patents are a kind of intellectual asset to whoever owns it, say, any individual or a company or it can be the government of a nation as well.

IPR Laws are getting more and more popular these days. It provides a relief to the innovative creators that their invention, idea, discovery will remain theirs. And among them, patent law is the most important. However, when it comes to medicine, which is an essential item for every individual, the same patent laws act as a blockage to the access of these essential commodities. This article deals with the meaning of pharmaceutical drugs, and it's patenting in India, along with problems that occurred because of it to the public access to health.

However, IPR culture in India is anything but satisfactory. It demands interest, in depth knowledge and effective strategies for encouraging and building IPR activities and explore scientific and industrial research and innovation in India.

KEYWORDS: PATENT, INNOVATION , HEALTH , IPR

INTRODUCTION

Among the developing world, India has long set an example by adapting its pharmaceutical laws to take into account domestic health needs, putting emphasis more on the needs of the general population, and thereby being aligned with its growth. Most of the Indian population lives below the poverty line, and the majority of medical expenses must be paid from one's own pocket, making it clear that the country is experiencing a severe health crisis due to inadequacies in healthcare, accessibility, affordability, and availability of medicines. The Indian patent law provides exclusivity under **Section 3(d).** 'By protecting access to medicine for the poor, the agreement strikes a great balance between its mandate and the Agreements on Trade Related Aspects of International Trade (TRIPS)'.[1]

This has undoubtedly been a notable change since TRIPS was implemented. A particular concern today relates to the pharmaceutical patent system in India. Indian pharmaceutical companies and the Indian market are major suppliers of low-priced pharmaceutical products such as generic drugs, which are essential to public health. India is a member of the Doha Declaration on TRIPS and Public Health, 2001, which has brought global implications for access to medicines over the past millennium. Having a pharmaceutical industry that is export-oriented and increasingly aware of civil society is essential for its development. Since the global access to medicines campaign began in India, it has been a regional leader. By demonstrating that an alternative pharmaceutical industry could be created, the Indian industry provided a backbone for the campaign. According to recent decisions related to Indian patent law, including the Novartis decision by the Supreme Court, India continues to place a high priority on public health in determining whether to grant patents for pharmaceutical products. The pharmaceutical patent system therefore restricts generic competition. As a result, prices rise and access to medicines in developing countries is hampered.

[1] Philippe Cullet, 'Patents And Medicines: The Relationship Between TRIPS And The Human Right To Health' (2003) 79 International Affairs https://www.jstor.org/stable/3095545

AN OVERVIEW OF INDIA'S IPR (intellectual property rights)

Human's mind creations are protected by intellectual property rights. Business today relies heavily on Intellectual Property since it represents the most important part of the business process as well as the commerce industry. IP is one of a company's most valuable assets. In turn, this can lead to more efficient development for manufacturers, traders, and owners of companies. So, intellectual property is the ownership of knowledge that individuals possess over the products of their brains. Several of these categories typically grant the creator a period of exclusivity over the use of their creation and follow it with recognition and monetary gain.

IMPLICATIONS AND MEANING OF PATENTS

The purpose of a patent is to grant exclusive rights to inventions, which, in general, are products or processes that offer a technical solution to a problem or introduce a new method for doing something. The application for a patent must disclose to the public the technical details of the invention.

Essentially, a patent is a type of intellectual property owned by the company or owner. Patents are granted for innovations that are original and unique to the person who invented it or to the group of people who did the invention.[2] A patent holder may recoup costs associated with development via this "exclusive right". It helps in the development of patented technology to retrieve a return on investment. In addition to stimulating research, effective patent protection is crucial to raising venture capital. Moreover, patent protection is critical to strengthening the economy as a whole. Patent applications should be filed by companies with a strategic approach that maximizes patent value while minimizing patent costs.

PATENTING IN PHARMACEUTICALS: WHAT IT MEANS

[2] 'Patent Landscaping' (Livelaw.in, 2021) <https://www.livelaw.in/law-firms/articles/law-firms-patent-landscaping-167378

Medications are created by pharmaceutical companies to treat diseases. The medicines are initially marketed under a trading name for the purpose of facilitating clinicians' recommendations to patients. Generally, a patent secures a drug, which means only the company holding the patent will have the right to produce, display, and, ultimately, profit from the drug. An approved drug is mostly patented for a period of 7 to 12 years after getting approval. This occurs because companies seek patents prior to conducting clinical trials to assess the effectiveness of the medicine. If the patent on the drug has expired, other companies can begin manufacturing and selling it. Drugs are known as generic drugs at this point.

LAW OF PATENTS IN INDIA AND PHARMACEUTICAL PATENTING

More than 60,000 generic brands are on the market in 60 therapeutic categories, the Indian pharmaceutical industry has a strong generic foundation. This foundation was shaped by the patent laws of the time. Indian economic success has been the growth of the domestic pharmaceutical industry. In the 1950s,[3] the Indian pharmaceutical industry was largely reliant on imports for survival. Today, it is recognized globally in this area as a manufacturer of high-performance, high-quality pharmaceutical products that are cost-effective. This company exports more than $1 billion a year. A drug and pharmaceutical patent system did not exist at that time, making this possible.

The term pharmaceuticals refers to pharmaceuticals, that is, products whose purpose is use as food, drugs, medicines, or substances derived from chemical processes(). The substance itself is not patentable, but only the process of manufacture of those substances is protected. Hence, Indian law does not currently provide patent protection for pharmaceutical products. In India, the Patents and Designs Act 1911 provided for the patent of all inventions. This was changed in 1970 when the new Patent Act came into effect. Pharmaceuticals and agrochemical products were not eligible for patent protection. Excluding bulk drugs and formulations from this list was done to break India's dependence on imports. Apparently, the goal was to develop an indigenous pharmaceutical industry that would be self-sustaining. Indian pharmaceutical industry has suffered a considerable impact due to the lack of product patent protection in pharmaceuticals and agrochemicals. Through it, enormous expertise was

[3] 'The Impact Of Patents On Innovation, Technology Transfer And Health: A Pre- And Post-Trips Analysis Of India's Pharmaceutical Industry' (2013) 19 New Political Economy.

developed in reverse engineering drugs which, in many industrialised countries, can be patented as products, but are not in India.

Thus, with the development of affordable versions of several patented drugs for the local market, India's pharmaceutical industry grew rapidly. As a result, generic drugs were aggressively entered into the foreign market with the expiration of international patents. Additionally, the Patents Act provides several safeguards to ensure that patent rights are not abused and that drugs are more accessible to consumers. Compulsory licensing is also covered by the Patents Act. Any interested party may apply for a compulsory licence in respect of a patented invention three years after it was sealed by the patent office. In any case, the patent controller can order the patent holder to grant this type of license upon the terms that they deem appropriate. He or she will only do this if he or she believes that the patented invention does not meet the reasonable expectations of the general public. or there is the unavailability of patented inventions at a fair price.

It is important to understand that u/s. 3(d) of the Patents Act, unless and until the individual or entity does not discover the new form of a substance which enhances its known efficacy, or if it is merely the a new property or method of utilizing the product, or, unless it is only the utilization of a known machine, apparatus or process provided that, it does not give a new product, or there isn't the introduction of at least a new reactant to the process, then it shall be deemed patentable under the said Section of the Patents Act. Countries across the globe can put a stop to the lacuna of evergreening, if they strictly follow the technological examinations and examining guidelines and the provision to S.3(d) that has been approved by the World Health Organization's 2006 Report on Public Health Innovation and IPR.

[4] With the Novartis case's ruling under Indian patent law, the community's access to affordable medicines is significantly improved in developing countries, and this will influence the access to medication for the poor. Novartis' victory would have probably led to more widespread approval of drug patents in India if they had won the case. In addition to restricting generic competition, it would also hinder access to affordable medicines in developing nations. Moreover, the practice is anti-competitive, as it enables pharmaceutical MNCs to eliminate generic competition. This allows patented pharmaceuticals to charge extortionate prices. Thus, the availability of essential drugs becomes inaccessible to the

[4] 'Patents And The Indian Pharmaceutical Industry - Intellectual Property - India' (Mondaq.com, 2019) https://www.mondaq.com/india/patent/865888/patents-and-the-indian-pharmaceutical-industry

general public in developing countries due to unaffordable pricing, resulting in adverse public health effects.

CASE LAW

Novartis AG v Union of India[5] was decided by the Supreme Court of India in 2013. Initially, the petitioner filed a patent application with the Chennai patent office in 1997. Glivec is a drug name derived from their 1993 patent for a leukaemia drug that was slightly different from the one used in this patent. An application for a patent under section 3(d) of the Indian patent act 1970 was rejected by the Assistant Controller of Patent and Design at the Chennai Patent Office. As a result, the petitioner filed a challenge before the Madras High Court challenging section 3(d).

Findings of the Court

A violation of the TRIPS Agreement is exclusively remedied through the WTO's Dispute Settlement override mechanism. When international law conflicts with municipal law, the High Court ruled that municipal law prevails. Indian law also does not directly recognize international treaties as binding. The court noted, therefore, that "Efficacy" refers to the effectiveness of getting the result desired. The test of efficacy will therefore differ according to the outcome the product is intended to produce, as per 3(d). Thus, its effectiveness would be determined by the product's function, utility, or purpose. In medicine, the only possible measure of efficacy is its therapeutic efficacy if it claims to cure a disease.

Accordingly, 'the Novartis patent application for the beta-crystalline form of Imatinib Mesylate failed Section 3(d) because no enhanced therapeutic benefit could be demonstrated. Thus, the Supreme Court affirmed the observations of the High Court and Indian Patent Office and dismissed the petitioner's patent application'.[6]

[5] 2013 AIR SCC 1311
[6] L Ndlovu, 'Lessons For The SADC From The Indian Case Of Novartis AG V Union Of India' (2015) 18 Potchefstroom Electronic Law Journal.

WHY AND HOW DO PHARMACEUTICAL PATENTS CAUSE PROBLEMS IN PUBLIC ACCESS TO HEALTH?

In India and abroad, there are differing viewpoints on how the government's move impacts the pharmaceutical industry. With a large number of pharmaceutical companies, India is ranked 4th in terms of production volume. The patents of pharmaceuticals are vital to fostering innovation. Meanwhile, this whole system of patents can be confusing to those who are not familiar with it. Patent monopolies are often abused by pharmaceutical companies and they charge unreasonably high prices for approved medicines. A product patent has significantly impacted the availability of medicine. It is difficult for the industry to produce life-saving drugs in India due to the patenting of many generic medicines, including vaccines.[7] Government expectations to protect citizens' health are in direct conflict with the exorbitant price of drugs that block ordinary citizens from accessing the medication. The healthcare system in India, where a large percentage of the population lives below the poverty line, and the healthcare costs are exorbitant, indicates that there exists a serious medical-care crisis with an insufficient supply of affordable healthcare and drugs which are readily accessible.

The Indian government faces a critical challenge. This is why they are taking a lot of action to protect the situation. As examples of alternate options, there is compulsory licensing (such as refusing voluntary licenses) and parallel trade policies. It can facilitate the affordability of essential medicines for citizens in developing countries. By creating competition for patented goods, compulsory licensing allows for lower prices for consumers. The primary function of this provision is to provide an organizational structure for various patent provisions that promote health. As a result, it also encourages the introduction of these provisions in countries that lack them. The second is that it raises the issue of competing claims between patentees and consumers. As of 1998, there were 4016 pharmaceutical companies fighting against the government of South Africa. Their arguments were that the Amendment to the Control of Drugs and Related Substances Act 17 violated their constitutional rights. By adding generic substitutes of off-patent medicines, transparency of pricing, and parallel

[7] Bhaven N. Sampat, Kenneth C. Shadlen and Tahir M. Amin, 'Challenges To India's Pharmaceutical Patent Laws' (2012) 337 Science.

importation of patented medicines, the Amendment Act created a legal framework for making affordable medicines available. I would have been interested to see how the court weighed the patentees' property rights against their health care rights if the case had gone to judgment. In particular, the state is constitutionally obligated to "take reasonable legislative and other measures to achieve the progressive realisation of" this right, within its abilities. Due to the fact that the case was withdrawn before it could be brought to trial, this issue remains moot.

APPROPRIATE SOLUTIONS FOR THE PROBLEM OF PUBLIC ACCESS TO HEALTH

One might wonder whether balancing pharmaceutical patents with the right to health is even possible. Is it really necessary to balance the right to health over less important and trivial trade norms if it is a fundamental right necessary for all other human rights?[8] Certainly. Health is one of the most important rights. The law must still provide some means by which innovators can protect their viable interests, which in turn will provide for their livelihoods. A balance must be struck between the interests of both innovators and the public. In my opinion, the pharmaceutical industry has been far too greedy in seeking stronger patent protection regardless of what the costs are, with a few exceptions. They consider TRIPS to be their most effective means of pursuing their profit-driven interests, thereby contradicting it. Specifically, even in TRIPS article 7, it is emphasized that producers and consumers of technological knowledge must be kept in balance. Various measures are taken to protect public health and nutrition in accordance with Article 8 of the Constitution while keeping in mind social and economic welfare.

Scholars have tried to conceptualize possible solutions by investing their time, effort and knowledge into proposing them. Additionally, PPPs and NGOs have conducted good practices in collaboration with large pharmaceutical companies. These groups are making great strides in enabling better access to medicine. The international community will have to decide whether these proposed solutions will be materialized and provide a long-term solution to those who desperately need one.

[8] Nilesh Zakharias, 'Patents And The Indian Pharmaceutical Industry - Intellectual Property - India' (Mondaq.com, 2021) <https://www.mondaq.com/india/patent/865888/patents-and-the-indian-pharmaceutical-industry

A) Existing solutions

Several existing approaches to resolving the conflict between access to medicines and the patenting of pharmaceuticals are discussed in this section. First, let me talk about the solution that has gotten international attention, namely the TRIPS flexibility of compulsory licensing. There are solutions such as legislative solutions, compulsory licensing alternatives and the Generic Competition alternative. The trick is implementing them correctly.

The TRIPS Agreement, which came into effect in India in 2005, is one of the most important agreements signed by important countries. India did not grant product patents for drugs before the TRIPS regime. In spite of strict patent regimes in developed countries, the generic drug industry flourished during that time in India. As a result, there was no problem with drug accessibility in India under this system. Likewise, even the drugs that were very expensive in other countries were very inexpensive in South Korea. It is important for developing nations to have access to drugs at very low prices. As a result, to ensure that compulsory licensing is not oppressive but not too liberal so that people tend to misuse drugs, the laws should be designed in such a way that they do not create obstacles to drug regulation.

(B) Possible solutions

Despite the fact that these solutions have been well-framed, they have failed to bring about any significant changes in this area. Due to this, a great deal of effort has been spent by many organizations and scholars in discovering alternatives that are acceptable for both sides. I will first present the solution that has been contested by the industry - price reductions for developing countries - which, if properly implemented, could significantly improve access to medicines. Price reduction, health impact fund, and good corporate citizenship are some of the possible solutions that can be suggested. By providing a fine balance, these solutions can be offered.

Pharmaceutical companies, patients, advocacy groups, prescribers, payers, and policymakers regularly discuss the cost of prescription drugs. Prescription drug costs are driven in part by the availability of competing products, but this is not the only factor. As a result of the patent

rights and/or exclusive marketing rights granted by the federal government to the innovator company, competitors' products, such as generics and biosimilars, cannot be made available immediately. It is intended to encourage innovation and development of new, safer, and more effective prescription medications by granting such exclusivity. The majority of drug prices can be reduced in this respect by bringing harmony between the owner and regulator of the patent.

CONCLUSION

As healthcare is organized in developing countries like India, fundamental rights are grossly violated. In the absence of basic minimum healthcare, the principle of justice is violated. Patented inventions enable industry and economic welfare only through localisation of their use. As a result, the inventive activity must result in innovation. Patent laws in India are among the best and aspire to balance inventor and common man interests. Patents can be obtained by pharmaceutical companies in India after the introduction of the product patent regime. Researchers should carefully consider the criteria of patentability before applying for a patent, and seeking advice from a patent expert is highly recommended in this regard. A patent right can be assigned or licensed to another person or company after it has been acquired. The use of patents can be an effective means of transferring technology to institutions that lack manufacturing capabilities or marketing capabilities. Companies could outsource the development of patented products and processes to third parties and earn revenue as a result of recouping the investment made in defining those products and processes. Licensed products can be marketed under certain conditions under a compulsory license. Despite development in the Indian pharmaceutical industry, the monetary interest of big players continues to threaten access to life-saving drugs at reasonable prices. It is critical to innovate and patent at the same time. In the medical field especially, innovation should serve humankind, and patents should not just be for profit.


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