Pharmaceutical Patenting in India: Problem of Public Access to Health

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INTRODUCTION

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. Clarifies that 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. According to 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 and access to medicines in developing countries is becoming more difficult.

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

The creation of the human mind is protected by intellectual property rights. Today's enterprises rely heavily on intellectual property because it is the most important part of business processes and the commercial industry. IP is one of the most valuable assets of a company. This can lead to more efficient development for manufacturers, distributors, and business owners. Intellectual property is therefore the ownership of the knowledge that a person has about the products of the brain. Some of these categories usually give the creator a period of exclusivity to the use of the creation, and then bring recognition and financial benefit.

IMPLICATIONS AND MEANING OF PATENTS

The purpose of the patent is to give the invention an exclusive right. An invention is generally a product or process that provides a technical solution to a problem or introduces a new process into something. The patent application must disclose the technical details of the invention to the public. A patent is essentially a type of intellectual property owned by a company or owner. Patents are granted for ingenious innovations that are unique to the group of people who invented or invented them.

This "exclusive right" allows the patentee to reimburse the costs associated with the development. We support the development of patented technology and improve the rate of return on investment. In addition to stimulating research, effective patent protection is important for raising venture capital. In addition, patent protection is essential to strengthen 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

The drug is being developed by a pharmaceutical company to treat the disease. The drug is initially marketed under a trade name to help doctors recommend it to patients. In general, patents guarantee medicines. That is, only the company that owns the patent has the right to manufacture, promote, and ultimately profit from the drug. Approved medicines are usually patented for a period of 7 to 12 years after being approved. This is because companies obtain patents and evaluate the effectiveness of the drug before conducting clinical trials.

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

With over 60,000 generic brands on the market in 60 treatment categories, the Indian pharmaceutical industry has a strong generic base. This foundation was shaped by the patent law of the time. India's economic success was the growth of the domestic pharmaceutical industry. In the 1950s, the Indian pharmaceutical industry relied heavily on imports to survive. Today, it is globally recognized as a manufacturer of high performance, high quality and cost effective medicines in this field. The company exports over $ 1 billion annually. This was possible because there was no drug and drug patent system at the time.

The term medicine refers to medicine. H. Products intended for use as foods, pharmaceuticals, pharmaceuticals, or substances derived from chemical processes (). The substances themselves are not patentable and only the process of manufacturing these substances is protected. Therefore, Indian law does not currently provide patent protection for medicines. In India, the Patent Design Act of 1911 provides for patents for all

inventions. This was changed in 1970, when the new patent law came into force. Pharmaceuticals and plant protection products are not covered by patent protection. The exclusion of bulk medicines and formulations from this list was done to break India's dependence on imports. Apparently, the goal was to build a self-sustaining domestic pharmaceutical industry. The Indian pharmaceutical industry has been severely affected by the lack of product patent protection for pharmaceuticals and pesticides. The result is a vast amount of know-how in reverse engineering pharmaceuticals. It can be patented as a product in many developed countries, but not in India. The Indian pharmaceutical industry has grown rapidly with the development of affordable versions of several patented medicines for the local market. As a result, the expiration date of international patents has expired, and generic drugs have been actively introduced into overseas markets. In addition, patent law provides several safeguards to prevent abuse of patent rights and to give consumers easy access to medicines. Compulsory licenses are also subject to patent law. Anyone who is interested can apply for a compulsory license for a patented invention three years after it has been sealed by the Patent Office. In either case, the patent officer may instruct the patentee to grant this type of license under the conditions he deems appropriate. He does so only if he believes that the patented invention does not meet the reasonable expectations of the general public. Or if the patented invention is not available at a fair price.

It is important to understand that u / s. Patent Law 3 (d) states, or simply uses, unless an individual or group is unable to discover a new form of known efficacy-improving substance, or is merely a new property or method for using the product. Except when you do. A known machine, device, or process is considered patentable under that section of patent law if there is no new product result or at least one new reactant has not been introduced into the process. Countries around the world adhere to technical research and research guidelines and the provisions of S.3 (d) approved by the World Health Organization's 2006 Report on Public Health Innovation and IPR. You can stop the gap.

The Novartis proceedings under Indian patent law have significantly increased community access to affordable medicines in developing countries, which affects poor people's access to medicines. Novartis' victory could lead to broader approval of drug patents in India if they win the proceedings

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

CASE LAW

Novartis AG v Union of India[1] 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).

The court found in this case,

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'.[2]

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.

Pharmaceutical patents are essential to drive innovation. In the meantime, this entire patent system can be confusing to those unfamiliar with it.

Patent monopolies are often abused by pharmaceutical companies and charge unreasonably high prices for approved medicines. Product patents have had a significant impact on the availability of medicines. Manufacturing life-saving medicines in India is difficult for the industry due to the patents of many generic drugs, including vaccines.

The government's expectation of protecting the health of its citizens is in direct conflict with the exorbitant drug prices that deny the general public access to medicines. India's healthcare system, where the majority of the population lives below the poverty line and medical costs are exorbitant, represents a serious health crisis with inadequate supply of affordable medical care and readily available medicines. increase. The Government of India faces significant challenges. For this reason, they are taking many steps to protect the situation. Examples of alternative options are compulsory licenses (such as refusal of voluntary licenses) and parallel trade policies. It can make essential medicines more affordable for citizens of developing countries. By creating competition for patented products, enforcement enables low prices for consumers. The main function of this provision is to provide the organizational structure of various patent provisions that promote health. As a result, it also encourages the adoption of these provisions in countries lacking them. Second, it raises the issue of competing claims between patentees and consumers. In 1998, 4016 pharmaceutical companies fought the South African government. Their allegation was that changes to the Narcotics and Related Substances

[1] *2013 AIR SCC 1311*

[2] *L Ndlovu, 'Lessons For The SADC From The Indian Case Of Novartis AG V Union Of India' (2015) 18 Potchefstroom Electronic Law Journal.*

Control Act 17 violated their constitutional rights. By adding general alternatives to unpatented medicines, pricing transparency, and parallel imports of patented medicines, the revised law is a legal framework for providing affordable medicines. is created.

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

You may even wonder if it is possible to balance pharmaceutical patents with right to health. If it is a fundamental right required for all other human rights, is it really necessary to balance the right to health with less important and trivial trade standards?

Certainly. Health is one of the most important rights. The law has not yet provided some means by which innovators can protect their viable interests and provide their livelihoods. There needs to be a balance between the interests of innovators and the general public. In my opinion, the pharmaceutical industry was very greedy for stronger patent protection, regardless of cost, with a few exceptions. They contradict it because they see TRIPS as the most effective means of pursuing profits. Specifically, Article 7 of the TRIPS Agreement also emphasizes the need to balance producers and consumers of technical knowledge. In accordance with Article 8 of the Constitution, various measures have been taken to protect public health and nutrition in consideration of social and economic well-being. Scientists have sought to come up with possible solutions by investing time, effort and knowledge in proposals. In addition, PPPs and NGOs work with major pharmaceutical companies to implement best practices. These groups are making great strides in providing better access to medicines. The international community needs to decide whether these proposed solutions will come true and provide long-term solutions to those in desperate need.

Possible Solutions-

This section describes some existing approaches to resolving conflicts between access to medicines and patents for medicines. First, I would like to talk about a solution that is attracting international attention, namely the flexibility of TRIPS for compulsory enforcement permits. There are statutory solutions, compulsory alternatives, and general competitive alternatives. The secret is to get them right.

The TRIPS Agreement, which came into force in India in 2005, is one of the most important agreements signed by important countries. India has not granted product patents for pharmaceutical products prior to the TRIPS regime. Despite strict patent regulations in developed countries, the generic drug industry flourished in India during this period. As a result, under this system, access to drugs was not a problem in India. Drugs that were very expensive in other countries were also very cheap in South Korea. It is important for developing countries to have access to medicines at very low prices. Enforcement is not oppressive, but legislation must be designed so that it does not interfere with drug regulation to ensure that people are not free enough to abuse drugs.

CONCLUSION

Basic rights are roughly injured because the medical system is organized in developing countries such as India. If there is no basic minimum health level, it violates the principle of justice. Patented inventions enable industrial and economic prosperity only through localization of their use. As a result, the activity of the present invention needs to lead to innovation. Indian patent law works with the best in order to balance the balance of inventors and the common interests of people. Patents can be obtained by Indian pharmaceutical companies after the implementation of the product patent system. Researchers should carefully consider the criteria for patentability before filing a patent application and are strongly encouraged to seek advice from a patent expert. Immediately acquired patents may be assigned or licensed to another person or company. The use of patents can be an effective way to transfer technology to institutions that lack manufacturing or marketing capabilities. Companies can generate revenue by outsourcing the development of patented products and processes to third parties and amortizing the

investments made to define those products and processes. Licensed products may be sold under compulsory licenses under certain conditions. Despite the development of the Indian pharmaceutical industry, the financial interests of large corporations continue to threaten access to life-saving drugs at reasonable prices. It is important to obtain innovation and patents at the same time. Innovation should help people, especially in the medical field, and patents aren't just for profit.

REFERENCE

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