PHARMACEUTICAL PATENTING IN INDIA: IPR PRACTICES AND LEGAL CONCERNS ON PUBLIC ACCESS TO HEALTH CONCERN

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ABSTRACT

Pharmaceutical drugs are made up of substances that are used to treat, diagnose, or cure a disease. In layman's terms, we call them medications. When we're told we have a disease, all we can think about is how to treat it with drugs. These treatments are now available to a larger percentage of the local community than they were previously due to recent advances in the pharmaceutical sector. Despite great progress, many people continue to struggle owing to a shortage of prescription prescriptions. Malaria, tuberculosis, and HIV/AIDS are three of Africa's most dangerous diseases for those who do not have access to medicine. More than half of all children globally die from pneumonia, diarrhoea, measles, HIV/AIDS, tuberculosis, and malaria. This is what the World Health Organization has to say about it (WHO). According to UNAIDS, the number of people dying from AIDS would approach 70 million if countries do not enhance their disease preventive strategies.

One of the world's most important accords on public health, innovation, and intellectual property was signed to solve this issue. As a response, the WHO and its partners have undertaken a number of initiatives to ensure that medications are available where they are needed. Many individuals feel the system is straightforward, but this is not the case. There are a number of problems that make it difficult for the WHO to meet its goal. Pharmaceutical patenting is one of the most difficult challenges to deal with.

Keywords – Patent, TRIPS, Pharmaceutical

INTRODUCTION

The Indian pharmaceutical industry relies heavily on generic medications. There are around 60,000 generic pharmaceutical brands on the market, covering 60 different therapeutic categories.[i] It was supported by the legal framework for patents in effect at the time. The growth of the Indian pharmaceutical industry is one of the country's most well-known success stories. In the 1950s, the Indian pharmaceutical industry was significantly reliant on imports. Today, the business is regarded as a low-cost supplier of high-quality, high-standard pharmaceutical items all over the world. It sells more than $1.5 billion in items each year. Because there was no product patent system for medications and pharmaceuticals at the time, this was plausible.

Because India is a member of the World Trade Organization, the TRIPS Agreement entered into force on January 1, 1995. (WTO). In order to comply with the TRIPS Agreement's standards, India has to give up some of its long-held beliefs regarding intellectual property.[ii] India was given a five-year transition period after the agreement was reached. Furthermore, India has been given five years to change its current patent laws governing medicine patent protection. As a result, Indian patent laws have changed:

- The Patents (Amendment) Act of 1999 - During the transition phase, more exclusive marketing rights were awarded.
- The Patents (Amendment) Act of 2002: Several changes were made to meet TRIPS standards.
- The Patents (Amendment) Act of 2005 is a law that amends the Patents Act of 1970. Before the Transition Period finishes, there will be numerous modifications.

Since 2005, all of these developments have occurred. It had a tremendous impact on India's patent rules. An important component of the Amendment was the repeal of Section 5 of the Patents Act, which specified that no patent may be granted for claims about substances used as food, medicine, or pharmaceuticals, as well as materials manufactured or produced by chemical processes. Chapter IV A, which detailed "Exclusive Marketing Rights," was likewise missing from the book. As a result of the changes, just one of them is still questionable.[iii] The argument revolves around Section 3(d) of the law, which aims to limit the availability of "secondary" pharmaceutical patents.

The rules for issuing a compulsory licence in India are defined under Sections 82–94 of the Patents Act, 1970, and Rules 96–102 of the Patents Rules, 2003.[iv] Under Section 84, the Controller of Patents may issue a "compulsory licence." This licence can be used to licence relevant patents under Sections 91, 92, 92-A, and 91.

PHARMACEUTICAL PATENTS AND PUBLIC'S HEALTHCARE

I. The Right to Health

Our Constitution also provides that we have a right to life, which includes a right to good health, as stated in Article 21. The right to life, according to the courts, includes the right to health and "access to medical treatment." The government should do everything it can to ensure that its citizens have access to life-saving drugs.[v] The state must not infringe on anyone's fundamental rights.[vi] To ensure that our Constitution balances social and economic rights, we need programmes.[vii] It is necessary to formalise the Preamble as well as the Directive Principles of State Policy (DPSP). The public's health as well as pharmaceutical businesses' economic interests must be addressed while setting patent restrictions.

Because India is a developing country, patents impose monopoly rights, prohibiting many people from receiving drugs, according to the Ayyangar Committee Report. Thus, regulations that confer monopolistic benefits are in violation of our Constitution's Preamble as well as Article 21, which declares that everyone has the same fundamental rights. Meeting the needs of its own people was given first priority. Gandhi, who was India's Prime Minister at the time, remarked that a better future is one in which medical discoveries are not patentable and no one profits from life or death.[viii]

Rich people spend a lot of money on research into new products and ways that can improve people's lives and allow them to live longer. People that make drugs now have a lot of influence. Medical advances would not be patentable, and there would be no profiteering from life or death in a better-run world.

II. The Patent and the right to health

Medicine is an important aspect of keeping people healthy. However, under the current administration, both the right and the means of obtaining it are under threat. Patents on

pharmaceuticals are critical in ensuring that people have access to the treatments they need to be healthy.

According to reports, if the patent system worked properly, the cost of these products would reduce while the cost of access would rise. Some have concluded that the global intellectual property system is in peril because patents may prevent people from receiving medicines and exercising their "right to health."

THE JUDICIAL PRECEDENTS ON PATENT VS HEALTHCARE

Natco Pharma Ltd vs. Bayer Healthcare Llc.[ix]

Natco Pharma is the first company in India to apply for permission to produce the generic version of Nexaver. Nexaver is a patented dug by Bayer Corporation. It's used to treat kidney and liver malignancies, among other things. Natco Pharma was awarded a compulsory licence for the same drug by the Indian Patent Office in 2012. They claimed that the medicine was not affordable to the common public and that it did not work in the country. To get a CL under Section 84, Natco Pharma had to meet three essential criteria. Nexaver costs $2,48,248 a month, which is worth noticing. Sorafenib Tosylate, the generic counterpart, costs $ 8800 per month.[x] The applicant was given the identical licence during the hearing, which the patent owner attempted to obstruct. The IPAB dismissed the patentee's appeal. Article 21 of the Indian Constitution provides that everyone has the right to be healthy. The IPAB took this approach to the case. They also looked into the major difficulties posed by Section 84(1) of the 1970 Patents Act.[xi]

F. Hoffmann-La Roche Ltd &Another v Cipla Ltd[xii]

A court order was imposed when Roche attempted to prevent Cipla from manufacturing the proprietary drug that Roche developed. An injunction was not issued by the Delhi High Court. According to the court, people have a right to life-saving drugs that are available and can be purchased. If the injunction is granted, they will be unable to obtain them. Obtaining a preliminary injunction would be exceedingly detrimental. If this happened, there would be little chance of improving life expectancy or even recovery for some individuals. An

injunction against a life-saving drug, as in the instance of Erloticip, would effectively suffocate Article 21 (of the Indian Constitution), which guarantees the right to life and is at the heart of the Indian right to health.[xiii]

Bayer vs Cipla

For more information on this case, see Bayer Corporation v. Cipla Union of India. This case sought to abolish the practise of tying medication marketing approval to the patent status of the original product, and not awarding marketing approval to any third party until the patent period ended unless the patent owner agreed. Bayer had a patent on "SorefenibTosylate," a kidney cancer drug that was offered for $2,85,000 for a month's worth of treatment.[xiv] Bayer has urged Cipla to stop making, selling, and distributing its own "Soranib" drug. The Delhi High Court held that the patent linkage system could not be applied to the entirety of the Drugs Act and Patents Act.[xv]

Novartis vs. The Union of Indian States

In the case of Novartis v. Union of India, the Supreme Court of India made a substantial change to pharmaceutical patents. Novartis has filed an appeal against the Indian Patent Office's refusal to grant a patent for beta-crystalline imatinib mesylate, a particular chemical. The patent was granted after the court found in Novartis' favour.[xvi] It's used to treat chronic myeloid leukaemia and is marketed by Novartis under the brand name "Gleevec" because it's made by them. After changes to the Patents Act were adopted on January 1, 2005, the appellant's patent application was removed from the "mailbox" for examination. Five pre-grant oppositions were filed against the patent application before it was ever evaluated, according to Section 25(1) of the Act.[xvii] The appellant presented affidavits regarding the bioavailability of imatinib mesylate in beta-crystalline form in response to objections expressed before the patent was issued. Everyone who wanted a patent on a product got their say on December 15, 2005. The Assistant Controller for Patents and Designs indicated under Rule 55 of the Patent Rules of 2003 that he or she did not intend to issue the product a patent.[xviii]

In his ruling, the Assistant Controller remarked that the appellant's claimed invention had been seen before, citing the Zimmermann patent as an example. He also stated that because of the description of the Zimmermann patent, the appellant's claimed innovation was obvious to a

person knowledgeable in the area.[xix] Even if the physical and chemical properties of beta-crystalline ImatinibMesylate were good, the Court held in this case that they would not be good for the Atomic Energy Part Test of the Act since those features could not be considered.

The court went on to say that other than the lawyers' clever arguments, there is nothing on that topic in this case. There is no evidence that the beta-crystalline form of ImatinibMesylate is more or less effective than the Imatinib free base in a Vivo-animal model. The Court further ruled that the beta-crystalline form of ImatinibMesylate did not meet the conditions for a patent, either as a set of standards for "patentability" or as an extension of the concept of "innovation." Here's how it went down:

The beta-crystalline form of ImatinibMesylate, for example, did not meet Section 3 requirements, according to the court (d). This did not stop the court from issuing patents to all incremental advances to chemical and medical substances under Section 3. (d). It would be a tremendous mistake to suppose that by eliminating Section 5 from the Parent Act, Section 3(d) was changed and the patent system was returned to its former position. It is unclear how this decision was reached. According to the court, the beta crystalline form of imatinib mesylate failed to meet both the innovation and patentability conditions set forth in Sections 2(1) and 3(d) of the Patent Act of 1970.[xx]

Because the majority of Indians are poor, they are unable to afford life-saving medications. On the other side, this decision has a major impact on the country's public health security. Novartis is unable to secure a patent for a new type of "beta crystal" for a well-known pharmaceutical, such as "imatinib mesylate," because this new type of "beta crystal" has not demonstrated new or improved treatment effectiveness. According to the court, a new type of drug must establish that it has more therapeutic effects or healing capacities than the old one in order to receive a patent. The reasoning was rejected by the court. It said that the qualities provided by Novartis could be useful for storage, but that it didn't have to show "improved therapeutic efficacy," as Novartis had claimed. The court did not, however, find that a new type of known drug could not be patented in this case. One thing is certain: a patent for a new type of known drug will never be issued. In this sense, the judgement is neither anti-patents or scientific and technological inventions, and it might serve as a model for other industrialised countries throughout the world to protect public health.

CONCLUSION

Whether through a variety of initiatives or by including a compulsory licence in the Patent Act of 1970, the government firmly encourages and promotes public access to medicines. The fact that the TRIPS agreement permitted for the establishment of a compulsory licence makes no difference. Previously, only method patents were available in India. No one else could use the same approach to create the patent or profit from it because it was a process patent. The same drugs or other things, on the other hand, could be made differently and offered under a new brand. As a result, they were well-known in India and prospered. Individuals need to be able to get medicines in public settings. Article 21 of the Constitution guarantees everyone the right to health care. All residents must have access to it, and the government must make it affordable.[xxi]

Problems with public access to medications, such as people's confusing decisions and the sector's capitalization, as well as medical practitioners' prejudices towards generic drugs, must be addressed. These problems must be resolved. Despite the fact that the policies have been put in place, they are not fully functional. This is due to Indian laws that make it impossible for anyone to obtain medications. The United States has a huge market for generic medications due to easy access to medicines and other policies. However, there are a slew of counterfeit pharmaceuticals on the market that are putting a stop to this trend. Generic pharmaceuticals are crucial for the health of the general populace in India, where income is low and out-of-pocket medicine costs are high.

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[(d) 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 a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation. -For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;]
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