Original Research Paper | Law | Volume : 6 ¦ Issue : 8 ¦ Aug 2021 ¦ e-ISSN : 2456-5040

INDIAN PATENTS ACT : A STUDY ON PHARMACEUTICAL PRODUCTS

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ABSTRACT

The field of intellectual property has grown in scope and complexity throughout the decades, as have the issues that arise in this area of law. Innovation and technical growth have facilitated development in practically every facet of life, including the pharmaceutical business. The pharmaceutical industry's intellectual property framework is mostly managed by patent laws and regulations. India has developed into the 'pharmacy of the world' over time, and it is critical that the Indian pharmaceutical industry operates under a robust intellectual property regime that supports research and development while also preserving the rights of patent holders in that arena.

KEYWORDS: Patent, Law, Intellectual Property.

INTRODUCTION:

Intellectual property is defined as intangible creations of human effort and intellect, and the rights obtained from the development of such property are referred to as intellectual property (IP) rights. These intellectual property rights are granted exclusively to the intellectual property's inventor. Because intellectual property comes in a variety of forms, its creator may be its author, owner, or inventor. While intellectual property is intangible and cannot be violated, the tangible, material form in which the intellect is expressed or represented must be safeguarded, which intellectual property rights provide. As with other types of property, intellectual property is an asset for its creator and so can be acquired, sold, licenced, and even assigned or gifted to others. The holders of intellectual property rights are the exclusive owners of these rights, and the intellectual property in respect of which the individual has IP rights cannot be utilised by anyone else without the individual's permission. Copyrights, patents, trademarks, industrial designs, and geographical indications are only a few of the forms of Intellectual Property Rights that are prominent in India. Intellectual property protection has taken on new dimensions in India and throughout the world over the last few decades. Many feel that a robust intellectual property (IP) regime can foster research and development activities that result in innovation, technical advancement, and economic prosperity. Among the several types of intellectual property rights, patents are used to protect inventions. They can be applied for by the inventor or any other person designated by the inventor. Patent is a negative right, which means that it does not grant the patentee (patent owner) the right to create, use, or sell the invention; rather, it grants the patentee (patent owner) the right to prevent or halt the use of his/her creation by third parties without his/her consent. Additionally, patents are available for inventions made in the pharmaceutical business, namely for medications and other products.

Patenting in the pharmaceutical sector has changed significantly and has a significant impact on people's right to health, particularly in developing nations. We will analyse the current state of pharmaceutical patenting and the developments brought about by international conventions regarding intellectual property rights in India in this paper.

THE INDIAN PATENTS ACT 1970:

This legislation, which was introduced in 1972, rendered pharmaceutical product innovations, as well as those for food and agrochemicals, unpatentable in India, resulting in a significant reduction in intellectual property rights protection. It made it possible for technologies that had already been patented elsewhere to be freely copied and promoted in India. As a result, foreign companies did not consider patenting in India to be beneficial. With the 1970 Drugs Price Control Order, this act further prohibited the importation of finished formulations, set high tariff rates, and established rigorous price control regulations for pharmaceuticals. The Indian pharmaceutical industry received a significant boost as a result of this.

India beyond 2004:

Whenever it comes to patents, a trade-off must be made between encouraging innovation while also incurring costs on behalf of the country that is providing the patent and the profits that accrue to that country.

Costs:

To make the most of his gains, the creator will raise the price of his drug now that it is protected by patents. As a result, fewer people will use the medicine. As a result of higher pricing linked with the introduction of product patents, Indian consumers will experience an indirect loss of welfare. Also included in these expenditures are administrative expenses such as handling infringement lawsuits and enforcing patent holders' rights.

Benefits:

Because the innovator stands to make more money, he or she is more likely to put more money into R&D and drug discovery and testing, which benefits consumers overall. Furthermore, patent rules mandate that specifications be made available to the public, allowing others to use new technology as a source of information for their own R&D. To make matters better, an inventing company can reveal its idea while maintaining control, allowing it to subcontract development work to countries like India for a lower price.

THE NOVARTIS CASE:

The Patent Act's Section 3 (d) limits access to secondary pharmaceutical patents, which are patents on novel forms of existing compounds and medications. This part had long been debated and acquired prominence in the case of Novartis AG vs Union of India. Through this decision, the Supreme Court of India has had a significant impact on pharmaceutical patents. This issue involves Novartis, a Swiss pharmaceutical corporation that manufactures the anti-cancer medicine 'Glivec,' which is patented in many other nations around the world. ' Following that, the medicine Glivec was distributed in India after receiving market approval, despite the fact that the patent application was filed in 1998. When the patent application was evaluated in 2006, multiple oppositions were made by domestic pharmaceutical companies such as Ranbaxy, Cipla, and others. The Madras Patent Office denied Novartis' patent application for 'Glivec,' claiming that the drug cannot be given a patent under the terms of Section 3 (d) of the Act because it lacks therapeutic efficacy above its present version, which is already patented outside India. Novartis was outraged by the order and filed two writ challenges with the Madras High Court under Article 226 of the Indian Constitution. Section 3(d) was challenged by Novartis on the grounds that it was incompatible with TRIPS, was arbitrary, irrational, and vague, and violated Article 14 of the Indian Constitution. The case was transferred from the Madras High Court to the Intellectual Property Appellate Board (IPAB). The Appellate Board heard the appeal and dismissed it on the grounds that the patent application fails to meet the requirements for innovation and non-obviousness for a patent. The court also determined that the medicine under consideration for patent does not have any therapeutic advantage over the prior patent, i.e. the Zimmermann Effect. The IPAB judgement was made in order to prohibit the continuous greening of existing patented items by making small changes to them. Later that year, Novartis petitioned the Supreme Court for a special leave to appeal the appellate board's decision. The Supreme Court also upheld the Madras Patent Officer's and IPAB's decisions and denied Novartis' special leave plea. This order allowed Indian companies to produce cheaper generic drugs for the treatment of blood cancer that would be affordable to third-world countries. Furthermore, the appeal board determined that under TRIPS, India has the right to protect public health and encourage universal access to medicines. Novartis charged Rs.1 20,000 each month for the dosage; however, the generic equivalent of this particular drug was accessible in India for a reasonable price of Rs.10,000. Article 27(2) allows members to reject some inventions that are necessary to maintain public order or morals, as well as human life. The judges in the Novartis judgement took into account many of the highlighted factors. The first factor was to uphold the legislature's intent in introducing section 3(d) to prevent ever greening of patents, which is a patenting strategy that involves acquiring patents on minor, often trivial, modifications to existing pharmaceutical products or processes in order to indirectly extend the period of patent protection over previously patented compounds. Novartis attempted to extend the patent's life by fil-

ing a patent application for the PETA crystalline form of 'Imatinib Mesylate.' As a result, the new version of the medicine would have a delayed patent expiration date, allowing Novartis to continue selling the drug even after the old version was no longer protected. In its interpretation, the Madras High Court stated that section 3(d) was enacted to prevent ever-greening in order to provide people of this country with simple access to life-saving drugs and to fulfil the constitutional commitment of providing good health care to its citizens. Section 3(d) was expressly designed to give patents for truly meritorious ideas rather than those that are simply enhancements on existing medications. During the course of the proceedings in this case, the judges concluded that Novartis had already recouped its R&D costs for the Glivec medicine in a relatively short period of time. As a result, the judges concluded that, because Novartis had more than earned the price for its research on the specific medicine, any future incremental innovation would have a significant impact on Indian society. Keeping in mind the interpretation of section 3(d), the judges of the Supreme Court also wanted to cut medicine prices and make health care more affordable for Indian citizens.

NATIONAL PHARMACEUTICAL PRICING POLICY, 2012:

Access to medicines is a major issue in nations like India where most people live below the poverty line. The cabinet adopted and notified the national pharmaceutical strategy in 2012, and a new medicine price control order in May 2013. The programme will bring various pharmaceuticals under the National List of Essential Medicines price regulation (NLEM). The new pricing strategy is intended to establish a regulatory framework to assure affordable access to essential pharmaceuticals on the National List of Essential Medicines. For All India,

As stated in Drug Action Network v. Union of India, the Indian government must ensure that citizens have access to life-saving medications. The National Pharmaceuticals Pricing Policy of 2012 intends to regulate medication costs based on drug essentiality through market-based pricing (MBP) of formulations rather than cost-based pricing (CBP) of bulk pharmaceuticals as the Drug Policy of 1994 sought to do. The new policy's primary features are:

The ceiling price for medications will be set by taking the simple average of all brands with a market share more than or equal to 1% of the total market revenue. The price cap would be based on dose per tablet, capsule, or typical injectable volume.

For the first time, the policy covers imported pharmaceuticals.

Patented drugs developed from indigenous products or processes have been protected from price regulation for five years. A formulation with a new delivery mechanism created by indigenous R&D would also be immune from price regulation for 5 years from the date of market approval. This may mean that certain vital drugs will be exempt from price regulation. On the surface, it appears to be designed to encourage pharmacy company investment.

Manufacturers might easily avoid price limitations by combining the necessary drug with another drug or a non-essential drug, but the policy addresses this problem by declaring that in such circumstances manufacturers must get pricing permission from the Government before marketing the new drug.

The policy specifies that the Government will ensure that their prices do not increase by more than 10% every year. The status of patented medications is currently undecided. A separate committee will set their rates.

CONCLUSION:

The Indian Patent Law is a model piece of legislation that addresses the numerous challenges associated with patents for new innovations. The TRIPS agreement made several changes to patent law in order to better safeguard the patent holder's interests. The application of product patents ushered in a new era in the country's pharmaceutical industry. On the one hand, the product patent regime benefited the original manufacturers of pharmaceutical drugs by allowing them to earn the necessary profits before the drug became generic, but it also created fear of pharmaceutical companies monopolising the market, making access to these medicines more difficult for the country's poor population. Although the new developments have prompted pharmaceutical companies to increase their R&D investments, which will result in the development of new pharmaceuticals for the benefit of humanity. However, the government must strike a balance between pharmaceutical industry research and public access to health medications. According to TRIPS regulations, governments may also establish provisions for the purpose of promoting public health standards, and in order to accomplish this goal, it would not be unreasonable to exempt certain pharmaceuticals from the patent law's rigorous regime. Section 3 (d) of the patent act is a novel provision designed to restrict the exploitation of goods patents through an ever-greening method. It assists local businesses in producing and distributing generic versions of pharmaceuticals once their patents expire and selling them at inexpensive prices. Compulsory licencing is also critical, as it aids in bringing the pharmaceutical drug to market if the patent holder does not appear to have met public interests over the prior years of its manufacturing. However, the absence of policy formulation is a shortcoming of forced licencing. Compulsory licencing terms are not sufficiently explicit for public guidance, and there is also a lack of understanding about it. The state should direct the controlling authorities to develop supportive policies that prioritise public access and benefits, while also ensuring that public access to health is not jeopardised at the expense of pharmaceutical industry research revenues.

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