



Scope of Patent Protection in Invention Relating To Public Health

Dhanvi Kollipara

Date of Submission: 11-05-2023

Date of Acceptance: 23-05-2023

An innovation is issued an exclusive intellectual property right by a government agency known as a patent. An innovation can be a commodity or a technique that gives a novel solution to a technological problem. The patent holder has the legal authority to prevent others from using or selling an innovation, but this privilege is only valid for a limited time. The major goal of creating such a patent system was to foster scientific advancements in practically all fields, secure global profit from such breakthroughs, and safeguard patent holders from exploitation.

PATENT AND PUBLIC HEALTH

The term "health" refers to a life devoid of illness or suffering, as well as a state of complete wellbeing not only physically but also psychologically and sociologically. The WHO, on the other hand, describes healthcare as design and execution of services and goods for the purpose of avoiding, curing, or monitoring any illness. A number of international treaties relating to IPRs and human rights lay the groundwork for patent rights as well as other types of IPRs.

This encourages new discoveries while also improving the welfare of a developing or underdeveloped country because these inventions can be applied to social or public welfare. Articles 14 and 21 of the Indian Constitution indirectly instruct the state to take steps to improve population health.

The objective of the patent law's limited monopoly is to assist the public, not only to import inventions.

The TRIPS Agreement established a brand-new, significant international framework for intellectual property rights, particularly in the health sector¹. The agreement stipulates that the invention's protection is only valid for 20 years. The requirements of the TRIPS Agreement must be adhered to by all WTO members. Nonetheless, each

nation is free to enact patent and intellectual property laws that suit its own demands for development and judicial structure.

Some duties that all parties had to uphold following the TRIPS agreement included:

1. To award the holder patent claims for at minimum 20 years from the date of application
2. Patents are used to recognise inventions in all disciplines of technology, with some exceptions.
3. To productively enforce patent law and patent holders' rights.
4. To implement forced licensing with restricted restrictions and conditions.

Two of the most pressing issues confronting developing or underdeveloped countries are the protection for public health as well as the creation of necessary medications. India is one of the countries experiencing a health crisis as a result of limited access to pharmaceuticals and healthcare services.

Because India is a developing nation that has a significant proportion of the people living in poverty, lawmakers introduced Section 3(d) to the Patent Act in 2005². This compromise between the TRIPS Agreement and the affordability of inexpensive medications for the needy has propelled India to the forefront of the Pharmaceutical Business.

India has emerged as a major producer in pharmaceutical items with affordable generic drug prices. Media coverage of the Supreme Court's Landmark Judgement in the Novartis Case³, which established the concept of greater efficiency defined in Section 3(d) of The Patent Act and prevents evergreening of patents, was observed not just in India but also Overseas.

The supreme court upheld the patent office's decision by rejecting the Novartis company's patent application and stating that enhanced efficiency refers to therapeutic efficiency and that modest drug improvements do not result in enhanced efficiency.

¹ WTO AND THE TRIPS AGREEMENT
https://www.who.int/medicines/areas/policy/wto_trips/en/

² Section 3 of Indian Patents Act, 1970.

³ Novartis AG v. Union of India, (Civil appeal no: 2706 – 2716) of 2013.



The Supreme Court also ruled that a new invention must be more effective in order to patent a drug that has already been developed. Due to India's transition to a product patent system from a process patent system in accordance with the TRIPS Agreement, Novartis' request for exclusive rights for the medication Gleevec was denied. This ruling received a priority on rulings involving pharmaceutical patent rights and public health. Low-cost medication availability in developing countries:

1. Compulsory Licensing: The TRIPS Agreement's Article 31 allow WTO Countries the power to impose compulsory licensing on patents, including Government use licensing, allowing anybody other than the patent holder to make use of inventions..

2. Parallel Import: Parallel importation is the practise of producing items covered by patents, selling them in one market, and then bringing them into a different market without the patent holder's permission.

3. Generic Medication: A generic version of drug contains the same active components as such product treatment. After the patents on original drug expire, consumers of Government agencies may acquire the off-patent drug.

4. Price Negotiation: The release of new drug makes it more challenging to buy them, especially for developing nations. These drugs can occasionally be very expensive. So, the nations attempt to bargain with the patentee to provide concession for those medications. So, the nations attempt to bargain with the patentee to provide concession on those drugs.

Eg: numerous pharmaceutical corporations provided HIV-AIDS medications to developing nations at the lowest possible cost.

CONSTITUTION AND PUBLIC HEALTH

Right to health isn't explicitly stated as a fundamental right in the Indian Constitution, yet it is supported by numerous constitutional judgements and legal opinions that promote right to health.

Some requirements to guarantee the right to health are contained in part IV of the constitution's DPSP's. In accordance with Articles 47 and 39(E) of the Constitution, the state is obligated to increase dietary standards and advance public health. Also, in the decided case *Bandhua Mukti Morcha v. Union of India*⁴, the Supreme

⁴ *Bandhua Mukti Morcha v Union of India & Ors*, (1997) 10 S.C.C. 549.

Court construed right to health as provision of Article 21 of the Indian Constitution⁵.

Throughout history, India has faced terrible medical crisis, which has worsened due to a lack of medicines and inadequate health-care facilities. Given these circumstances, pharmaceutical companies have to offer the patented medication at reasonable price.

The Indian Patent Act of 1970 included various provisions to find a balance among public health and patentee rights while addressing public health issue and establishing a robust public health system. The following is a list of the provisions:

1. Section 47 of the Act authorises the state to purchase or make use of any patented product or patented technique for public good. In the event that a medication or drug has a patent, the government is authorised to utilise the product or distribute it to any dispensary, hospital, or other medical facility. This provision ensures that the public's health and well-being remains a priority and those in need have access to the medications or drugs necessary for their care.

2. Section 83 of the Indian Patents Act of 1970, the issuance of a patent should not compromise public health protection and must secure that the patented product is offered to the public at a reasonable price.

3. Section 84 states that "After three years from the date of patent grant, compulsory licensing is required. This provision aims to protect the public interest by establishing specific requirements under which anybody can apply for the licence by submitting an application to the controller. The reasons behind this are as follows:

(i) "That the reasonable requirements of the public in respect to the patented invention have not been satisfied,

(ii) That the patented invention is not available to the public at affordable prices,

(iii) That the patented invention is not worked in the territory of India."⁶

In the judgement of landmark case *Bishwanath Prasad Radhey Shyam v Hindustan Metal Industries*⁷, Supreme Court held that: "The object of patent law is to encourage scientific research, new technology and industrial progress.

⁵ Nishant Sirohi, Declaring the right to health a fundamental right, (22nd February 2023, 20:00 hours), <https://www.orfonline.org/expert-speak/declaring-the-right-to-health-a-fundamental-right/>

⁶ Section 84 of Indian Patent Act, 1970

⁷ *Bishwanath Prasad Radhey Shyam v Hindusthan Metal Industries AIR (1982) SC 1444*



Grant of exclusive privilege to own, use or sell the method or the product patented for a limited period, stimulates new inventions of commercial utility. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which after the expiry of the fixed period of the monopoly, passes into the public domain.”⁸

PHARMACEUTICAL PATENT CLASSIFICATION

One of the most intellectually stimulating industries, the pharmaceutical companies, could be very costly and unforeseen in the terms of study cost and outcomes. The result of pharmacological industry can be unique, creative, or useful. Without a doubt, such a market is likely to be highly competitive; thus, it is critical to provide pharmaceutical companies with a way of protecting their goods from unauthorised commercial exploitation through the use of patent rights. According to the Indian Patent Office, these public health patents fall under a number of areas, including:

1. DRUG COMPOUND PATENTS⁹

The chemical make-up of a drug component, which has the broadest protection conceivable, is asserted as a patent in this category. It is claims that can have multiple "functionally comparable" chemical units occur in more than one component of the compound in question. This claim is sometimes referred to as a Markush Type claim.

A similar medicine cannot be directly or indirectly created by another company with a similar business model before the relevant patent expires.

2. FORMULATION PATENTS¹⁰

This patent category permits the use of technology in the formulation of a drug's active components. This is meant to imply that a special mixture utilised to prepare an active ingredient in the creation of the quantity that will be given to the person could be protected under this category.

3. PRODUCT BY PROCESS PATENTS¹¹

It defines a product in light of the manufacturing technique. This kind of patent is usually given when the product cannot be characterised or differentiated from patent claims other than the referral to the manufacturing method.

4. TECHNOLOGY PATENT¹²

Companies may employ a variety of inventive approaches to address certain technological issues; therefore these breakthroughs also necessitate extensive protection. Technology patents can be useful in this situation. This category can be used to safeguard solutions such stability, improved solubility, taste masking, etc.

CONCLUSION

A novel medicine typically requires extensive research, high-cost clinical trials, and significant financial expenditure. Giving the patent holder exclusive rights is a way to reward the inventor. When both the public and private sectors are involved in innovation, That is essential for developing Nations, public health goals can be reached. The promotion of general health and simple access to healthcare services would be made possible by international cooperation.

The Indian Government should take proactive steps to guarantee access to medical care and to create healthcare programmes in the medical sector to the people who are in need. It ought to make significant investment in all facets of research and development and work to develop more reasonably priced medication. As a result of implementing a TRIPS Agreement provision, India is now one of the world's top producer of pharmaceutical products. Also, the state should motivate the public sector to handle and support technological research across all disciplines.

In light of this, it is obvious that public health is a crucial component of India's patent laws. The availability of pharmaceutical drugs at reasonable prices not only provides flexibility to the public, but also balances demand for an essential product.

⁸ Ibid.

⁹ Arushi Goyal and Disha Moitra, Striking a Balance between Patent Laws and Public Health Issues with Special Emphasis on its Recognition in India. (23rd February 2023, 10:17 hours) <https://www.ijlmh.com/paper/striking-a-balance-between-patent-laws-and-public-health-issues-with-special-emphasis-on-its-recognition-in-india/>

¹⁰ Ibid.

¹¹ Ibid.

¹² Ibid.