INDIAN JOURNAL OF LAW, POLITY AND ADMINISTRATION

ISSN: 2582-7677

PHARMACEUTICAL PATENTING AND DIFFICULTY IN ACCESS TO PUBLIC HEALTHCARE IN INDIA

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ABSTRACT

The patent is one of the significant Intellectual Property Rights used in the pharmaceutical industry. In the era of globalization, the scope and ambit of patent expanded and reached new dimensions. The patents are granted to encourage innovation and simultaneously ensure that innovation is available to society. Although when it comes to pharmaceuticals, the same patent laws obstruct access to public healthcare. One of the important questions is how to balance the interests of private pharmaceutical companies and public health in developing and underdeveloped countries, especially during public health emergencies such as HIV/AIDS, treating cancer and the one that we are all currently facing – Covid19. This paper deals with patenting pharmaceutical drugs in India and the challenges in access to healthcare and medicine during health emergencies.

Keywords: Patent, Healthcare, Pharmaceutical, Covid19

(I) Introduction

Pharmaceutical medicines are substances that are used to treat, diagnose, or cure illnesses. In layman terms, we simply call them medicines.[1] The development in pharmaceutical industry owes much to research and innovation. Recently, in the last few decades, intellectual property, especially patents, has to be seen as an enabling factor for pharmaceutical innovation.[2] When we are diagnosed with a disease, we seek medical care which is under our reach and capability to afford. However, with recent advancements in the pharmaceutical industry, as big pharmacy companies mostly care about

[1] https://study.com/academy/lesson/pharmaceutical-drugs-definition-types.html.
[2] https://www.iam-media.com/commercialising-pandemic-how-balance-patents-and-public-health-emergencies.

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profit, the medical facilities are getting access to only rich people who can afford it, especially in developing and under-developed nations. It is the organization like WHO and governments of the country who has to regulate this business accordingly so that the public health care shall reach every person in the world. Poor shall not feel helpless due to lack of medical facilities and higher prices of essential drugs in the time of health emergencies and otherwise.

Although scientific and technological innovation has contributed to significant improvements in health conditions, health crises, relating, in particular, to HIV/AIDS, malaria, tuberculosis, etc continue to create major problems in many parts of the world.[3] In country such as India, a considerable part of the people are living in poverty that are not in condition to meet daily healthcare expenses and it significantly shows that there is a health crisis with inadequacy of resources with respect to affordability, availability and accessibility of the medicines in India.[4]

Article 25(1) of Universal Declaration of Human Rights states that *"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control".*[5]

In the State of Punjab vs. M S Chawla, it has been held that-the right to life ensured under Article 21 incorporates inside its ambit the right to health and clinical consideration.[6] Even after all this codification by world organizations, state legislature and judiciary, at the time of health emergencies like the covid19, the situation is more than worse in India, it is inexpressible and it seems that country's public healthcare system has been doomed. The collapsed healthcare system of India can even be seen by the government data of deaths.

The issue of public health was addressed at the fourth World Trade Organization (WTO) ministerial conference in Doha in 2001. The Doha Declaration confirmed the absolute right of governments to take measures to protect public health by creating provisions for WTO member

[3] https://www.wipo.int/patent-law/en/developments/publichealth.html.
[4] https://allindialegalforum.in/2021/02/01/pharmaceutical-patenting-in-india-and-the-problem-of-public-access-to-health/.
[5] https://www.un.org/en/about-us/universal-declaration-of-human-rights.
[6] https://blog.ipleaders.in/right-health-part-article-21/.

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countries to issue compulsory licenses to export generic versions of patented medicines to countries with insufficient or no pharmaceutical manufacturing capacity, as well as to allow parallel imports.[7]

Even after knowing the facts of Doha declaration, no one knows why India has delayed this much and still delaying in evoking compulsory licensing for Bharat Biotech's Covaxin (Covid19 vaccine) and several other useful drugs for the recent pandemic of covid19.The Doha declaration on TRIPS (Trade related intellectual property rights) and public health confirms that governments have the right to freely determine the grounds of issuing compulsory licenses.[8]

Patent and innovation are two sides of the same coin. Innovations should be for assisting the humanity exceptionally in the domain of medicine and patents should not have only one objective to accumulate profit.[9] Pharmaceutical patents restrict the generic competition and thus increase prices, and are thought to be a significant barrier to access of medicines in developing countries.[10]

(II) Evolution of Patent Law in India

Intellectual property rights are legal rights that are granted for the creations of human intellect. These rights allow the creator to enjoy the fruit of his hard work, endeavor and patience. At the beginning of the 21st century, the scope of these rights expanded and reached new dimensions. The significance of intellectual property (IP) was recognized even in the ancient period. Moreover, the industrial revolution also raised IP in certain areas. These developments ultimately resulted in the universal recognition of IP, and many countries granted legal protection to the innovations and creations.

Patent - Meaning and Importance: A patent is an exclusive right granted for an invention. In other words, a patent is an exclusive right to a product or a process that generally provides a new way of

[7] https://www.iam-media.com/commercialising-pandemic-how-balance-patents-and-public-health-emergencies.
[8] http://timesofindia.indiatimes.com/articleshow/82468175.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst.
[9] https://allindialegalforum.in/2021/02/01/pharmaceutical-patenting-in-india-and-the-problem-of-public-access-to-health/.
[10] https://ili.ac.in/pdf/paper5.pdf.

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doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application.[11]

Patent is perhaps one of the most important intellectual properties available to pharmaceutical companies. When a pharmaceutical firm develops a treatment for a clinical condition, it is first sold under a brand name so that professionals may recommend it to patients. The medicine is protected by a patent, which means that only the pharmaceutical business that owns the patent can manufacture, market, and profit from it in the long run.

Pharmaceutical Patenting: When a pharmaceutical firm develops a treatment for a disease, it is first sold under a brand name so that professionals may recommend it to patients. The medicine is protected by a patent, which means that only the pharmaceutical firm that owns the patent can manufacture, market, and profit from it in the long run.

Indian Patent Act 1970: The Patents and Designs Act 1911 used to provide a product patent regime for all inventions. In 1970 meanwhile, the government passed the new Patents Act (Indian Patent Act 1970), which made pharmaceuticals and agrochemical goods ineligible for patent protection. This exclusion was enacted to reduce India's reliance on imports for drugs and to promote the development of a self-sufficient domestic pharmaceutical sector, and break the hegemony of big foreign pharmaceutical companies for whom India was a good haven and market for their business.

As a result, the Indian pharmaceutical sector flourished substantially by manufacturing less expensive copies of several patented drugs for the domestic market and then aggressively expanding into the international market with generic medicines once the patents expired. Furthermore, the Patents Act establishes several measures to avoid patent infringement and improve medicine accessibility.

India was an early signatory to the General Agreement on Tariffs and Trade (GATT).[12] Although, it is clear that GATT favored wealthy nations over underdeveloped countries. During the Uruguay Round discussions, certain developing nations, particularly Brazil and India, advocated that

[11] https://www.wipo.int/patents/en/faq_patents.html.

[12] India signed the GATT on July 8, 1948, and became a founding member of the World Trade Organization on January 1, 1995. As a result, India joined the TRIPS Agreement on January 1, 1995.

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GATT had no business dealing with matters of intellectual property protection, which should be considered at the World Intellectual Property Organization (WIPO). At the time of negotiations, it was decided that nations at various stages of development should have their freedom to determine whether or not to issue patent rights to particular items throughout the discussions; India joined the World Trade Organization (WTO).

The TRIPS Agreement came into force on 1st January, 1995 and India as a member of the WTO was required to comply with the provisions of the TRIPS Agreement. As a developing country, India obtained a 5-year transition period[13] and an additional 5 years to amend patent laws on patent protection of pharmaceuticals.[14]

Amendment of 1999: The Patents (Amendment) Act, 1999, came into force on 1st January 1995. The Amendment of 1999 added Chapter IVA after Chapter IV of the Patents Act, 1970, to regulate exclusive marketing rights specifically.[15] After a couple of years, On May 20th, 2003, the Patents (Amendment) Act was enacted. Many provisions of the Indian Patents Act, 1970, were amended to comply with TRIPS standards. The changes were the definition of the invention, the object of patent protection, the patent term, the patent application requirements, compulsory licensing, and the bolar exception, all of which had a major impact on India's pharmaceutical patent system.[16]

Amendment of 2002: The TRIPS Agreement specifies that patents shall be accessible for all inventions, whether products or processes, in all branches of technology, provided that they are novel, entail an inventive step, and are capable of industrial application.[17] As a result, the 2002 Amendment specifies an invention, a new product or process involving an inventive step and capable of industrial application, and further define inventive step as a feature that makes the invention not obvious to a person skilled in the art.[18]

[13] TRIPS Agreement, Article 65.2.
[14] TRIPS Agreement, Article 65.4.
[15] Indian Patent (Amendment) Act, 1999.
[16] Indian Patent (Amendment) Act, 2002.
[17] *TRIPS Agreement*, Article 27.1.
[18] Indian *Patent (Amendment) Act*, 2002, Section 3(f).

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The 2002 Amendment extended the term of protection of all patents to 20 years in compliance with the TRIPS requirement.[19] The Amendment has made a number of revisions to the compulsory license provision in compliance with the TRIPS Agreement and the Doha Declaration. It clarified the grounds for a compulsory license, that any person interested may apply to the Controller for a compulsory license for a patent at any time after the expiration of three years from the date of the patent's sealing on any of the following grounds: (1) that the public's reasonable requirements for the patented invention have not been met; (2) that the patented invention is not available to the public at an affordable price; and (3) that the patented invention is not worked in the territory of India. The third ground was added as a result of the Amendment.[20]

Moreover, the amendment also provides a special provision for compulsory licenses on notification by the Central Government,[21] which may be issued in a circumstance of national emergency, health emergency (like the recent one of Covid19), or a case of public non-commercial use, including public health crises, relating to HIV/AIDS, tuberculosis, malaria, or other pandemics like Covid19. At the same time, the amendment also provides for the termination of a compulsory license by the Controller,[22] if and when the circumstances that gave rise to the grant thereof no longer exist and such events are unlikely to recur.

Bolar Exception: The TRIPS Agreement stipulates that members may provide limited exceptions to the exclusive rights conferred by a patent.[23] The Amendment included a stipulation that certain conduct, known as regulatory exceptions, would not be deemed infringement. According to this provision, without the patent owner's authorization, generic pharmaceutical producers can use the patented invention to get market approval from a regulatory agency for medicines and healthcare items. The Bolar exception is another name for this rule.

[19] Indian Patent (Amendment) Act, 2002, Section 27(a).
[20] Indian Patent (Amendment) Act, 2002, Section 39 and 84.
[21] Indian Patent (Amendment) Act, 2002, Section 39 and 92.
[22] Inian Patent (Amendement) Act, 2002, Section 39 and 94.
[23] TRIPS Agreement, Article 30.

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Amendment of 2005: The Amendment of 2005 was crucial for India to implement the TRIPS obligations fully. The omission of Section 5 of the Patents Act, 1970, is the most significant modification introduced by the Amendment.[24] Which provided that no patent shall be granted in respect of claims for substances intended for use or capable of being used, as food or as medicine or drug or relating to substances prepared or produced by chemical processes?[25]

The Amendment also made essential adjustments to the provisions on compulsory licenses and extended the scope of application of the Bolar exception to importation.[26] This means that marketing, constructing, using, selling, or importing a patented invention solely for purposes reasonably related to the development and submission of information required under any law in India or elsewhere that regulates the manufacture, construction, use, sale, or import of any product is not considered an infringement of patent rights. This provision focuses primarily on pharmaceuticals and medical devices.

(III) Pharmaceutical Patenting in India

With hundreds of generic brands in the market, the Indian pharmaceutical business has a solid generic base. The Indian pharmaceutical sector has established itself as a cost-effective producer of high-standard and high-quality pharmaceutical products. This was possible because, from 1970 to 2005, there was no product patent system for pharmaceuticals and drugs, and patents were only issued for the process of manufacture of such substance, not for the substances themselves.[27] As a result, the Indian pharmaceutical sector expanded quickly by manufacturing less expensive versions of several patented drugs for the domestic market and finally moving aggressively into the international market with generic drugs once the international patents expired.

Importance of Pharmaceutical Patent: Obtaining patent protection is essential to safeguard the innovative approaches used by pharmaceutical companies. The pharmaceutical patent helps in recovering investments that are incurred during the research and development stage. Also, these

[24] Indian Patent Act, 1970, Section 5.
[25] Indian Patent (Amended) Act, 2005, Section 4.
[26] Indian Patent (Amended) Act, 2005, Section 58(a).
[27] Indian Patent Act, 1970.

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patents can secure against infringement cases, as competitors can easily duplicate the manufacturing of a drug. The pharmaceutical patent helps raise venture capital, which, therefore, improves the overall economic growth of companies operating in this industry.

Indian Patent Act, 1970 and Pharmaceutical Patent: As previously stated, the Indian Patents Act has evolved over time, particularly after India ratified the TRIPS agreement. In 2016, the government announced the New IPR Policy with 7 main objectives,[28] but they did not seek to change the provisions of the Indian Patent Act, 1970. India emphasized that it complies with TRIPS, which establishes minimum standards for intellectual property protection.

The distinctly contended section in the Act is Section 3(d). Section 3(d) of the Indian Patent Act, 1970 prevents ever greening of patents in India by providing that '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 is not an invention, and hence cannot be patentable.[29]

Majorly an invention can only be patented for 20 years. After the patent period is over, other firms can create these products at a far reduced cost. Normally, pharmaceutical companies strive to keep their patents alive (ever greening) by making minor changes to the original product, but Indian law has stricter standards. The case Novartis AG v. Union of India[30] elucidates this condition.

Another provision is Section 84, which provides for compulsory licensing. After three years, any person interested can make an application to the controller for the grant of compulsory licensing, or the government can authorize the third party to produce any patented product without the need of permission of the patent owner,[31] mostly during the national or health emergency (like the covid19 pandemic). The TRIPS agreement legitimizes the notion of compulsory licensing, which is widely used in the pharmaceutical industry by various countries. In India, though, the provision hasn't been invoked frequently; this is the right time to induce compulsory licensing.

[28] https://yourstory.com/2016/05/new-ipr-policy-india/amp.
[29] India Patent Act, 1970.
[30] Novartis AG v. Union of India, (2013) 6 SCC 1.
[31] Indian Patent Act, 1970.

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Novartis AG v. Union of India: This is one of the significant cases of Section 3(d)[32]. The Supreme Court, in this case, rejected a patent grant for Swiss pharmaceutical company Novartis for its anti-cancer drug Glivec.[33] Glivec is used to treat Chronic Myeloid Leukemia.

Novartis' claim was dismissed by the patent office on the grounds that it was hit by Section 3(d) of the Indian Patents Act, 1970 and that the drug had no recognized clinical efficacy over its previous version. The company challenged this, and the Supreme Court heard the issue. The court had to examine the following points:

1. Is the innovation covered by Section 3(d)?
2. Interpretation of Section 3(d)?

The Supreme Court held that Glivec was a new substance and not an entirely new substance. As a result, it failed to pass the Section 3 test (d). The clause cites increased effectiveness as a requirement; however, this was not met.

The court held that only because it was beneficial to some patients does not mean that the medicine had met this standard. The court also observed that in cases of life-saving drugs, a more stringent condition needs to be applied while granting a patent to protect the lives of the masses. As far as possible, ever greening must be prevented.[34]

Impact of Novartis Case: The case had a huge impact in the country and the rest of the world. As the patent for Glivec was rejected, its price fell from Rs 1,50,000 to Rs 6,000.[35] This fall in price helped save the lives of close to 5,00,000 patients in India, according to YK Sapru, Head of Cancer Patients Aid Association.[36]

Internationally also, Novartis created a huge uproar. A report by the UN Secretary-General encourages other WTO members to utilize the flexibility under TRIPS and set stringent conditions for

[32] Indian Patent Act, 1970.
[33] https://blog.ipleaders.in/analysis-novartis-g-vs-union-india/.
[34] https://www.khuranaandkhurana.com/2020/01/23/an-analysis-of-the-indian-patents-act-with-respect-to-the-pharmaceutical-industry/.
[35] https://www.ip-watch.org/2018/05/20/five-years-indian-supreme-courts-novartis-verdict/.
[36] https://www.khuranaandkhurana.com/2020/01/23/an-analysis-of-the-indian-patents-act-with-respect-to-the-pharmaceutical-industry/.

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patentability, because of increasing access to medicines. NGOs in countries like South Africa and Thailand were encouraged by the case and rallied for similar standards in their respective countries.[37]

(IV) Problem in access to Public healthcare in India

The Indian Patent Act of 1970 is sufficiently adaptable to deal with a wide range of prospective public health concerns. For decades, India has been burdened by different health crises, the most of which have been caused by insufficient healthcare facilities and lo access to medicines. At the same time, it serves as a crucial supplier of low-cost pharmaceuticals drugs in the form of generic medicines.

Paragraph 4 of the Doha Declaration prioritizes public health over Intellectual Property rights. It clarifies that this extends to medicines and vaccines, diagnostics, and other health tools as required,[38] but pharmaceutical companies frequently abuse patent monopolies.

The emergence of product patents has hampered drug accessibility. Absurdly high prices prevent common people from accessing medicines, which go against the government's stated goal of protecting citizens' health. Especially in a nation like India, where a big portion of the population lives below the poverty line and healthcare prices are excessive, there is an evident life threatening emergency with inadequacy in terms of healthcare and the price, affordability, and accessibility of drugs

"About 55 million Indians were pushed into poverty in a single year because of having to fund their healthcare mainly due to spending on medicines alone".[39] Though the government pledges to deliver low-cost medicines through the Jan Aushadhi outlets, they too have their own set of issues. The patent system works effectively in the West, because most people have health insurance; customers pay a premium to insurance firms in return for coverage, avoiding the high expense of medicines. In developing and undeveloped nations, where the majority of the population is uninsured, this is not the case because everyone cannot afford health insurances or med claim.

[37] https://www.ip-watch.org/2018/05/20/five-years-indian-supreme-courts-novartis-verdict/.
[38] https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
[39] https://timesofindia.indiatimes.com/india/health-spending-pushed-55-million-indians-into-poverty-in-a-year-study/articleshow/64564548.cms.

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There was little incentive for patients to seek public healthcare as the availability of free drugs in the government health system for outpatients was shrinking and their availability for inpatients was sharply declining, according to the study, which also noted that medicine-related household expenditure remained high as most patients sought outpatient care in the more expensive private sector.

At a different point in life, we all must have heard that "Health is Wealth". As human beings are social animals so we like to live in a society, which at large creates a nation. To manage this large society of people, known as a 'Nation', we have different ways to run a country, among which democracy is one of the most prevalent these days. Citizens pay taxes for the nation's development and in return expect good medical, educational, and other facilities whenever required. Formally, WHO and Constitution of India acknowledge the 'Right to health' as a fundamental right,[40] but it has been seen otherwise in India through years. Covid19 has revealed the Indian public healthcare system; people are dying and dead bodies are floating in the holy river. Lack of ICU beds, oxygen cylinders, ventilators, healthcare staff, hospitals, medicines (Remdesivir, Fabiflu, etc.) could only be seen during a pandemic in India. Cruel private healthcare facilities, people in debt due to medical treatment, helplessness of people, and the dead bodies is the new normal. Positivity and decent healthcare are accessible to a handful of people in India.

(V) Conclusion and Suggestions

Patents and public health are two sides of the same coin. Improving public health standards by making pharmaceutical products easily accessible at minimal costs does not restrict patenting for pharmaceuticals but instead attempts to balance the two. Patents should not be to collect wealth, and innovations should be in the best interests of humankind, especially in the medical profession. Healthcare in developing nations like India has created conditions for severe violations of fundamental rights. When the majority of the population lacks access to primary healthcare, the principle of justice is compromised. Inventive activity should lead to innovation, which leads to technological advancement and industrial and economic prosperity, which is only feasible through the local application of patented innovations. The Indian Healthcare Industry is strained with many

[40] Constitution of India, Article 21.

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issues, but there are problems within the existing system as well. Section 3(d) remains underutilized in India, the government should also consider using Section 84 (Compulsory licensing) effectively, specifically in times of pandemic like - covid19.

Many decisive and major steps needs to be taken to improve public healthcare of India, like – Increasing healthcare budget, investing more on R&D, building new government hospitals, establishing dispensary in every village, utilize man power of a country in a productive way, ensuring public healthcare to every citizen of the country, making healthcare a priority, recruiting more healthcare staff and acknowledging value of human life.