



I P BULLETIN

Vol. II (02), July-Dec 2021, pp. 40-50



INTELLECTUAL PROPERTY RIGHTS AND HEALTH: ISSUES OF ACCESS AND PRICING OF MEDICINES

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ABSTRACT

Health is the greatest possession that an individual acquires. Whenever a person is denied a right to health, it becomes an infringement of his/her fundamental right. The research paper seeks to examine that times when right to health is often denied to a section of society because of the reasons of high pricing of medicines. Intellectual property right is a legal right that is given to a person for his creativity or invention. One of such intellectual property right is Patent. A patent right is given to an inventor of a particular product and is considered as one the important intellectual property rights as it aims to promote innovation and invention in a country. The pharmaceutical medicines or drugs are the subject matter of patenting and thus, it becomes difficult for normal public to access the essential medicines at reasonable prices. The reason behind this is the monopoly that is created among the pharmaceutical companies due to the grant of patent to their product and process. The research paper takes a dig into various issues of access to medicines and over pricing of the same that arises because of patenting. The paper then seeks to determine the challenges faced by the poor section of the society. To sum up, the research paper concludes that the patent system will benefit greatly and serve the technological and economic advantages, only after the negative impact of the patent system is properly assessed

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Keywords: Patent, pharmaceutical drugs, access to medicines, intellectual property rights, overpriced medicines.

INTELLECTUAL PROPERTY RIGHTS

Legally speaking, there are two broad categories of Properties. One is the tangible property and the other is intangible property. A tangible property is a kind of property that physically exists but intangible property are the properties that lacks physical substance. The denomination ‘Intellectual Property’ usually comes under the category of intangible properties. The reason being that an Intellectual Property is in a general sense, a creation and invention of a human mind. The word Intellectual Property is a combination of two very generic terms. One is Intellectual which means the ability to think and understand ideas at a high level, whereas on the contrary another term is the property which means a thing that belongs to somebody. This collectively provides us a definition of Intellectual Property which means something which is created with the help of a human intellect. A huge amount of effort, time, and skill is put in by an individual to create and invent something new and distinct. And this is the reason why the concept of Intellectual Property has gained enormous popularity. As there are some rights that are entrusted in other property owners, similarly, there are a number of rights that are bestowed in an Intellectual property owner. These rights are the Intellectual Property rights. Intellectual Property, very broadly, means the legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields. Countries have laws to protect intellectual property for two main reasons². On the basis of the creation of human mind, following are the different types of Intellectual Property rights-

A. Copyrights

Copyright can be defined as an exclusive right granted by law to the author of a work to disclose it as his own creation, to reproduce it and to distribute or disseminate it to the public in any manner or by any means and also to authorize others to use the work in specific ways.³ In simple terms, a copyright is a kind of intellectual property right that is

² *Understanding Copyright Laws: Infringement, Protection and Exceptions*. Available from: https://www.researchgate.net/publication/301890434_Understanding_Copyright_Laws_Infringement_Protection_and_Exceptions [accessed Jan 26 2022].

³ Asherry Brian Magalla, The true meaning of copyright (2015), Intellectual Property and Development of Science and Technology, available from: https://www.researchgate.net/publication/283015654_THE_TRUE_MEANING_OF_COPYRIGHT [Accessed Jan 26 2022]

given to a creator of any literary or artistic works. In India, the term Copyright is defined under Section 14 of the Copyright Act, 1957, which provides a long list of work which can be subjected to copyright. A copyright can be obtained for musical works, cinematographic works, artistic drawings, paintings, novels, books, architecture, dramatic works etc. The creator of such work is termed as the true owner of the copyright. For the owner to obtain a copyright, it is essential that he converts his ideas into a tangible form. Only then he can get his creation protected otherwise not. The purpose of the copyright is to secure and reward the general benefits i.e. labour of authors on the produced work. It encourages the authors to produce and proceed with more works on continual basis.⁴

B. Trademarks

A trademark as the name itself suggests is a mark that is used in the trade. The object of the trade mark is to make the goods of a manufacturer or trader known to the public as his and thereby enable him to secure in course of time such profits as may accrue from the reputation which he may build up for his goods by superior skill, efforts and enterprise.⁵ This is a category of intellectual property right which vests rights in the trademark users so that their mark is differentiated in the market and based on which are consumers are attracted and rely over such manufacturers. A trademark can be used for the benefit of the business. The concept of trademarks and the law governing the use thereof owe their origin to business competition, practice and custom.⁶ Trademarks can be a name, number, logo, coined term, colors or combination of these and could be the texture or shape of the goods too.⁷ Trademark means a mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person from those of others and may include the shape of goods, their packaging and combination of colours.⁸ A trademark is granted for a term of 10 years.

⁴Understanding Copyright Laws: Infringement, Protection and Exceptions. Available from: https://www.researchgate.net/publication/301890434_Understanding_Copyright_Laws_Infringement_Protection_and_Exceptions [accessed Jan 26 2022].

⁵ Chakraborty, Rahul, Growth of Intellectual Property Law and Trade Marks (January 31, 2009). Available at SSRN: <https://ssrn.com/abstract=1335874> [accessed Jan 26 2022].

⁶ Ibid.

⁷ Geejo Francis, Law of Trademarks in India (2011), SSRN Electronic Journal, available from: <http://dx.doi.org/10.2139/ssrn.1850364> [accessed Jan 26 2022].

⁸ Section 7, Trademark Act, 1999, India.

C. Industrial Design

The creative activity of achieving an ornamental or aesthetic appearance of mass produced products or articles is covered under industrial design. The design can be expressed either by two dimensional or by three dimensional forms.⁹ An industrial must be new or original for the purpose of getting protection under the category of intellectual property rights. 'design' means only the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article whether in two dimensional or three dimensional or in both forms, by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye.¹⁰

D. Geographical indication

Another type of Intellectual Property Right is a Geographical indication which helps a consumer to know that a particular product derives from a specific region or geographical area. In simple terms, by geographical indication, one can clearly and easily differentiate between the qualities of the products based on their land of origin. For a geographical Indication to be protected as an Intellectual Property right, it is important for an individual to establish a nexus between the product and the region. A geographical Indication tag is often granted for products such as handicrafts, foodstuffs, wines, alcoholic beverages etc.

E. Patent

A patent is the granting of a property right by a sovereign authority to an inventor. This grant provides the inventor exclusive rights to the patented process, design, or invention for a designated period in exchange for a comprehensive disclosure of the invention.¹¹ A patent is a document that is given by the Government of India to any inventor so that his invention is protected from any unauthorized usage.

⁹ Lalit Jajpura, Bhupinder Singh, Rajkishore Nayak, An Introduction to Intellectual Property Rights and their importance in India Context (2016), Journal of Intellectual Property Rights, Vol 22, pp32-41, available from: <http://docs.manupatra.in/newslines/articles/Upload/41C26FED-7AFE-40EA-8736-4E6C516917AE.pdf> [accessed Jan 27 2022].

¹⁰ Section 2, Design Act, 2000, India.

¹¹ Will Kenton, Patent (updated April 2021), Investopedia, available from: <https://www.investopedia.com/terms/p/patent.asp#:~:text=A%20patent%20is%20the%20granting,comprehensive%20disclosure%20of%20the%20invention> [accessed Jan 27 2022].

PATENTING IN PHARMACEUTICAL INDUSTRY

As there had always been a technological as well as industrial advancements in the country, the concept of Patent also has simultaneously evolved with time. One of the major industries that is enjoying the benefits and the right that comes along with Patent, are the Pharmaceuticals. This is so because each day a new drug is being introduced in the market and the Patent right is given to the same. Patents are granted to those inventions which are new, is an inventive step and is capable of applying in the Industries. A Patent provides an exclusive right to the Patentee to use, sell, re-sell, license its products for a time period of 20 years. It is upon the patentee how he uses his invention in order to gain economic and financial growth. The Pharma Industry is one such example. There is a wide range of Pharmaceutical Patents in India namely, Drug Compound Patent, Composition Patent, Synergistic Combination Patent, Technology Patents, Polymorph patent, Process Patent, Biotechnology Patent etc. The Patent Act, 1970 sanctions pharmaceutical products to be patented in India, if it qualifies all the criteria required to get itself patented. A pharmaceutical industry is an important one, so much for its economic size as for the benefit that it delivers to users of its product.¹² Patents contribute to roughly 80% of the overall revenue of pharmaceutical companies and obtaining patent protection is important to safeguard the innovative approaches used by pharma companies.¹³ Drug patents help recoup investments that are incurred during the research and development stage. Also, drug patents can secure against infringement cases, as competitors can easily duplicate the manufacturing of a drug. Drug patents help raise venture capital, which thus, improves the overall economic growth of companies operating in this industry.¹⁴

An invention to be protected under the Patent laws has to fulfil unquestionable criteria. An invention should follow the rule of Novelty. Novelty in general sense means any product which is new and usual. So, for an invention to obtain a patent, the first condition is that the invention is completely new and original, meaning that the invention is something which have

¹² Caves, R. E., Whinston, M. D., Hurwitz, M. A., Pakes, A., & Temin, P. (1991). Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry. Brookings Papers on Economic Activity. Microeconomics, 1991, 1–66. <https://doi.org/10.2307/2534790>

¹³ Shilpi Kumari, Patents in Pharmaceutical industry (2020), S&A law offices, available from: <https://www.mondaq.com/india/patent/900672/patents-in-pharmaceutical-industry#:~:text=Patents%20contribute%20to%20roughly%2080,the%20research%20and%20development%20stage> [accessed Jan 27 2022]

¹⁴ Ibid.

never been disclosed and have not been used earlier. The second important condition to be fulfilled is that the invention is non-obvious. This means, the invention is such that in an ordinary circumstance, any skilled person cannot recreate the same. So, in order to match with the second important eligibility criteria, the invention is a whole new inventive step.

The last element which is required to obtain a patent protection is that the invention is capable of being used in the industries. There shall be an industrial application of the invention. When an invention qualifies all the above stated criteria, then only a product or an invention has the right to apply for patent protection, otherwise the granting of protection is rejected. Any pharmaceutical drug or medicine, also, have to undergo the same eligibility test. After enacting, Patent Act, 1970 by the Indian parliament, it became easier for the pharmaceutical companies to get their medicines patented. Not only the process patent, but the product patent was also one of the chief characteristics of the act. By providing Patenting in pharmaceutical industry, has helped the Indian medicine company to grow and develop at a large scale. The benefits arising out of Patenting for pharmaceutical industry can be enlisted as follows-

- a) Patent stimulates invention. As one can protect its invention, so they can concentrate on the making of new and innovative drugs which is obviously good for the public health.
- b) Patents on medicines are expected to give social benefits by inducing more innovations.
- c) Patents helps to provide incentives to the companies.
- d) Patent on medicines and pharmaceutical drugs aids to higher economic growth in the country.

In order to avoid risks prevailing in the market, the patent owner or the inventor can provide license to an individual, company or companies, probably to those who have a better knowledge of the competitions in a global market. Compulsory licensing is also one of the kinds of patent licensing. In case of Compulsory licensing the government grants permission to the companies to make, use and sell the patented product, without the prior permission of the patent owner. This is done for public welfare. For pharmaceutical medicines and drugs, the government grants compulsory license to the pharma companies, so that the essential drugs are made available to the public at large. Compulsory license can be provided to the companies, only if the three conditions are fulfilled. The first and the foremost condition is

that there is a surplus demand of the patented product. The second condition is that the patented product is not available to the general public and the last condition is that the patented product is not from within the territory of the country where such demand is made. Whenever, such circumstances arise in a country, the government can provide compulsory license to the companies. Usually such category of license is reserved by the government for the pharmaceutical products.

RIGHT TO HEALTH IN INDIA

Right to health means that any individual residing in the country should have an access to the health care system. Right to health is treated as one of the important human rights. Human rights are the natural rights that are available to them merely for the reason that they have been born as a human being on this planet. These are the basic rights which every human being will have from the time they are born till the time they die. Right to health, also, comprises the same category of right, which refers to that every individual will have a right to access the health care services in the time of emergencies and otherwise. The concern of right to health is not a national issue but this has been a topic of relevance at the international level as well. Evidently, the World Health Organization, speaks by the way of its preamble that each individual has a fundamental right to the enjoyment of the highest attainable standard of health. This means that the WHO also makes it very clear that right to health is not only a basic human right but it shall be treated as one of the primary fundamental rights too. Health is a state of complete physical, mental and social well-being and not merely the absence of the disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.¹⁵

Right to health at the international levels

The right to health is entrenched in a series of international treaties as well as numerous national constitutions. A major international standard-setting instrument is the International Covenant on Economic, Social and Cultural Rights (ICESC).¹⁶ Additionally, the right to health is recognized, inter alia, in article 5 (e) (iv) of the International Convention on the

¹⁵ Constitution of World Health Organization (WHO), available from: https://www.who.int/governance/eb/who_constitution_en.pdf [accessed Jan 29, 2022].

¹⁶ Seema, Right to health in India: Law and Practice (2015), Department of Political science, Aligarh Muslim University, available from: <http://hdl.handle.net/10603/40578> [accessed Feb 01, 2022]

Elimination of All Forms of Racial Discrimination of 1965, in articles 11.1 (f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women of 1979 and in article 24 of the Convention on the Rights of the Child of 1989. Several regional human rights instruments also recognize the right to health, such as the European Social Charter of 1961 as revised (art. 11), the African Charter on Human and Peoples' Rights of 1981 (art. 16) and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 (art. 10). Similarly, the right to health has been proclaimed by the Commission on Human Rights.¹⁷ The notion of Right to health contains four elements in its ambit- availability, attainability, acceptability, quality.

Right to health at the national level

In India, right to health is not explicitly included under any of the enumerated fundamental rights of the constitution. But this does not mean that India do not consider the value of right to health. For that very reason, right to health in India is often included under Article 21 of the Constitution of India. Article 21 of the Indian Constitution talks about Protection of persona life and liberty, which means no one shall be deprived of his life or personal liberty. The Supreme Court of India, through its progressive interpretation of the Constitution has effectively included the right to health as an integral part of the right to life (Article 21) which is a fundamental right.¹⁸ Through a number of cases like the *Bandhua Mukti Morcha v. Union of India*¹⁹, *Consumer Education and Resource Centre v. Union of India*²⁰, *State of Punjab and Others v. Mohinder Singh*²¹, the Supreme Court of India, justifies that what all conditions and elements can be taken into consideration while determining right to health. Recognizing health care as a basic human right assumes that medical services are viewed as a natural right of all people and not a privilege of some fortunate individuals.²²

¹⁷ Committee on Economic, Social & Cultural Rights resolution 1989/11, as well as in the Vienna Declaration and Programme of Action of 1993 and other international instruments. The United Nations General Assembly in 1991 resolution 46/119

¹⁸ Prabakar K, Right to health in India and Judicial Concern: A critical analysis (2020), Department of law, University of madras, available from: <http://hdl.handle.net/10603/345096> [accessed Feb 01, 2022].

¹⁹ AIR 1997 SC 2218.

²⁰ AIR 1995 SC 992.

²¹ AIR 1997 SC 1225.

²² Supra note 17.

ISSUES AND CHALLENGES OF ACCESS AND PRICING OF MEDICINES

Patent is a monopoly right which promotes the advancement of science and technology by conferring a title upon an inventor to make, use or sell the invention, only for a constrained limited period. Drugs and pharmaceutical items may be patented but the exclusivity promised by a patent may cause hardship on the part of the public due to the higher price of the branded drug. This has caused political strife across the world.²³ The patenting on medicines create monopoly in the market. A monopoly is a dominant position of an industry or a sector by one company, to the point of excluding the other viable competitors.²⁴ This means that if one pharmaceutical company is manufacturing, producing and selling a particular type of medicine, the exclusivity that is guaranteed to a patented product, makes it difficult for the general public to use such medicines. This is so because of the high prices fixed by such companies. Also, if taken into consideration, the concept of Compulsory Licensing, then also the medicines and the drugs that are imported in our country yields high prices because of the monopolies of the Pharmaceutical companies. This creates a challenge in the access of the medicines, when the question of right to health arises. The access to at least essential medicines shall be easy. Providing monopoly rights under patents for pharmaceuticals will block access to life-saving drugs and the patent holder can increase or decrease the price according to his own choice.²⁵ This monopoly results in the overpricing of the medicines. Right to health also includes access to health related information. Drug companies often abuse the patent monopoly and fix exorbitant prices for the patented medicines. The introduction of product patent thus reduces accessibility and affordability of drugs.²⁶ The major section of the society that is affected by such patenting on medicines are the poor people who cannot afford a proper lifestyle. The product patent provides an exclusive right to the patent owner, and this exclusivity is what leads to the non-accessibility of medicines as well as over pricing of the same. While the pharmaceutical industry claims that high prices are explained by the massive

²³KOCHAVA R. GREENE, "WHAT IS DRUG PATENTING?", Available from: https://www.google.com/search?source=univ&tbm=isch&q=Kochava+R.+Greene,+%E2%80%9CWhat+is+Drug+Patenting?%E2%80%9D,available+at:http://www.ehow.com/about_5052330_drug-patenting.html&sa=X&ved=2ahUKEwi_lprOh6TpAhWQIbcAHcDPD-wQsAR6BAgCEAE&biw=1366&bih=625 [accessed Jan 28 2022]

²⁴ Adam Hayes, what is Monopoly (2021), available at <https://www.investopedia.com/terms/m/monopoly.asp> [accessed Jan 29, 2022].

²⁵ Gurpreet Singh, Compulsory licensing in Pharmaceutical industry- a threat or a necessity (2021), available from: <https://blog.ipleaders.in/compulsory-licensing-pharmaceutical-industry-threat-necessity/> [accessed Jan 29, 2021].

²⁶ G. Dutfield, Intellectual property rights and the life science industries: Past, present and future, 2nd ed. (Singapore: World Scientific Publishing, 2009), pp. 315–316.

expenditure on R&D, the truth is that drugs they actually research have little relevance to real medical needs. Moreover, the kinds of profits that big pharmaceutical MNCs generate are an indication of profiteering and not just legitimate profit making.²⁷

CONCLUSION

There is an unclear answer to the question of whether the benefits of patents on medicines have indeed exceeded costs. The patent system will benefit greatly and serve the technological and economic advantages, only after the negative impact of the patent system is properly assessed.²⁸ Right to health is considered to be one of the basic rights of a human being. And clearly, if they cannot access to the basic medicines, this right seems to fail in a democratic country. In order to ensure a better health care system in a country, few initiatives are required relating to the over pricing of the medicines. The World Health Organisation, which is one of the agency of United Nations that connects the world to promote health, also in its constitution have stated that right of access to health care medicines and services are basic fundamental right and it shall be made available to each and every individual, without making any discrimination on the basis of economic or social living standards of the people. So, if at all by the means of patenting on medicines, the rich get an access to the pharmaceutical drugs and the poor are denied the access on the basis of over pricing, this leads to the failure of what United Nations preaches the world. Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households.²⁹ The design of a health care system in any country must be guided by the following key human rights standards: access, availability, acceptability, quality and non-discrimination. Human rights are used proactively as a tool for provision for better healthcare. The right to health care thus ensures that hospitals, clinics, medicines, and physician's services are accessible, available, acceptable and of good quality for everyone, on an equitable basis. It defined health

²⁷ Rahul Vicky, Right to health vis-à-vis Patent Protection: The Indian Scenario (2015), academike, available from: [https://www.lawctopus.com/academike/right-health-vis-vis-patent-protection-indian-scenario/#:~:text=The%20right%20to%20life%20and,\(TRIPS\)%5Biii%5D](https://www.lawctopus.com/academike/right-health-vis-vis-patent-protection-indian-scenario/#:~:text=The%20right%20to%20life%20and,(TRIPS)%5Biii%5D) [accessed Feb 01, 2022].

²⁸ M Rahmah, Social cost and benefit of patent protection for medicines: Case of Indonesian seaweeds hard capsule invention, *Utopia y Praxis Latinoamericana*, vol. 25, no. Esp.2, pp. 171-178, 2020, available from: <https://doi.org/10.5281/zenodo.3809208> [accessed Jan 29, 2022].

²⁹ Supra note 15.

in terms of an ultimate goal of perfection.³⁰ Since patents on drugs tend to push prices up, governments have a duty to ensure that the introduction of product patents does not jeopardize access to drugs. Indeed, not only should states refrain from taking any steps that limit access to drugs but also they should also actively pursue better access over time.³¹

³⁰ Jonathan Montgomery, *Health Care Law*, Oxford University Press, Oxford (1997), p.2.

³¹ *Supra* note 26.