

**Human Right to Health v. Patent Right in the light of TRIPS Agreement**

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## ABSTRACT

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*Intellectual property is intangible property. It is the result of man's intellectual creation and labour combined. The creator of such a novel idea or the inventor is assured certain rights concerning his invention and how it is being put to use by others known as Intellectual Property Right (IPR). A patent is one such right granted to the creator of a novel product or process involved in any industry for the technological advancement of that industry. The Indian pharmaceutical industry is an immense knowledge-driven sector which demands a lot of cost and efforts for pharmaceutical research, the reward for which is pharmaceutical patenting. However, it has its share of challenges. This article attempts to throw light on various challenges faced by the Indian pharmaceutical industry because of its membership in the TRIPS Agreement relating to the introduction of the new product patent regime. Also, understand how it has affected the accessibility and affordability of medicines to poor and how section 3(d) of Indian Patent Act, 1970, has helped achieve a balance between the patent right of drug manufacturers and the right to access healthcare of poor.*

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**Key Words:** Patent regime, evergreening, Synergistic combination Patents, Technology Patents, Polymorph Patents, Pharmaceutical patent

## INTRODUCTION

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Intellectual property is intangible property. It is the result of man's intellectual creation and labour combined. It is a unique creation which is novel and is useful for the society. The invention acquires protection by certain rights concerning how others can exploit it. Anyone can use his idea. However, such use is subject to his terms and conditions, the very rationale for granting him those exclusive rights. There are various forms of intellectual property viz, Trademark, Copyright, Patent, Design, Geographical indication, and so on. The primary focus of this paper is patent. Thus, it will be discussed in detail.

A patent is an exclusive right granted by the government of respective territory to the applicant for any invention which can be used and applied in any industry to solve any technical problem for a term of 20 years. It is a negative right granted to the owner because he can prevent others from making unauthorized use, offer for sale, sale, or import without his permission. A patent is a territorial right that means it can be enforced only in the country where its granted. A right to patent protection of an invention can be granted to only those inventions that satisfy a particular criterion such as it should be a new and unique, capable of being applied in industry and should add to the technical advancement.

By its membership in WTO, India signed the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement in 1995, compelling it to amend its patent law from time to time. One of them being amendment for procedure and conditions for filing of product patent applications regarding drugs and agrochemicals with effect from 1 January 1995. Initially, the patent in India was granted only for process invention. However, since 2005, the product patent is also being allowed.

The outcome of Pharmaceutical research can result in a new, innovative, and useful product or process for which patent can be known as Pharmaceutical patenting. There are different kinds of Pharmaceutical Patenting such as Drug compound patents, Formulation/ composition Patents, Synergistic combination Patents, Technology Patents, Polymorph Patents, and so on.

## HUMAN RIGHT TO HEALTH VS PATENT RIGHT

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Ever since the introduction of the product patent regime, a wide variety of pharma products have begun earning patents in India beneficial to the owners immensely. However, in a country like India, where a humongous population lives below the poverty line, patenting has posed a severe threat in terms of affordability and accessibility as a consequence of rising healthcare services costs. India has been one of the world's largest low-priced pharmaceutical products suppliers for ages throughout the world's poorest countries that benefitted the nation economically. The product patent has restricted the competition between generic medicines that led to the rise in costs, thus acting as a barrier in access to poor people, specifically in developing countries like India. (William, B., 2017)

India, is the world's largest supplier of the low-priced generic medicines, producing the same medicine as the U.S at a price that is 100 percent cheaper than that of U.S. Also, it exports its medicines at comparatively high yet reasonable prices to countries like Brazil, Russia, Southeast Asia, Middle East and other poor countries of the world. (Dogra, T. 2020). But because of the product patent regime, the Indian pharmaceutical industry couldn't thrive that well in the overseas drug market due to increased patent restrictions globally, which significantly affected India's export sector and income enjoyed therefrom. What India had been perceiving as the ideal economic status quo since then in the pharmaceutical sector was adversely affected by the inevitable mandate imposed on it by WTO TRIPS. (Tancer, R., 2005).

Apart from hitting the country's economy hard, the new TRIPS regime posed a problem of availability and affordability of medicines to the poor as well. The availability and affordability of preventive and curative pharmaceutical products are the two major problems encountered by the developing countries because WTO made it mandatory for its member countries to make amendments in their domestic patent laws to allow both product and process patents in their pharmaceutical industries. (Watal, J., 2000). The population of third world countries and developing countries have been suffering life-threatening diseases that have been neglected despite the gravity they pose. The product patent has indirectly led to monopoly pricing powers between manufacturers of generic medicines that shot the prices that common man can never afford under their patent protection. Also, the Medicines with better product patent deals offered were manufactured ignoring the medicines for life-threatening diseases thus affecting the accessibility to the poor.

According to the Black's Law Dictionary, health means, "freedom from pain and sickness, the most perfect state of animal life and the natural agreement and concordant disposition of the parts of the living body".(Black's Law Dictionary, 2020). According to World Health Organisation Report (2000), Health care is defined as "the prevention, treatment, and management of illness and the preservation of health through the services offered by the medical, nursing and allied health professions". Access to affordable healthcare facilities has been understood to be a fundamental human right available to every individual irrespective of the territory they reside as put forth by constitutions of many countries like India, the US. China, etc. and also various international organizations such as UDHR, ICCPR, etc. These international treaties and covenants cast a duty on the nations to preserve the health of their people by ensuring they are not denying access to quality healthcare facilities at any stage and are enforceable by their people as a legal right. Thus, it is pertinent to note here that there is a clash between the new TRIPS product patent one of the amendments regime and the right to accessible health care. However, a step towards striking this balance between articles of the TRIPS Agreement and affordability of cheap medicines to poor people in developing countries has been, to some extent at least, in the opinion of the author, has been achieved by enacting section 3(d) of the India Patent Act. This section mentions that the criteria for granting product patent are that the product should demonstrate significantly high levels of efficacy and those inventions which are exceptionally meritorious alone can be patented and not all. This section ensures that patents aren't granted for every trivial invention and by keeping the scrutiny levels high, the competition among the manufacturers to produce better quality products increases thus benefitting the end consumers penultimately. Also, it makes sure that not a larger portion of generic medicines are protected by patent thus ensuring that only a small portion of products are patent protected and thus a little beyond affordability of the poor while the rest remain affordable and accessible to the poor.

Further, this section ensures prohibition of the illegal yet legal concept of 'ever-greening' which means the manufacturers of the drugs change the product composition slightly to increase the product's patent protection duration and thus trying to show that the product can never expire. (Horner, R. 2013)

Hence while the TRIPS article broadens the scope for obtaining product patent, section 3(d) of Indian patent law narrows down the chances of obtaining product patent thus ensuring there's a balance between the patent rights of the manufacturers and the poor people's right to health.

## **CONCLUSION AND SUGGESTIONS**

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There used to be and there still are debates existing constantly between people seeking justification of IPR implementation and why a strict IPR regime is to be followed and on the other hand people who are concerned about the health and welfare of the public at large.

Thus, there arises a need to recognize the enormous importance of public health and also the need to strike a balance between rights of the patent owner and the users of such invention (medicines in this context) for which patent is granted. Even the articles of the TRIPS Agreements put forth that the objective of the agreement is the protection of effective use of Intellectual Property Rights along with technological advancement and mutual benefit of both producers and users with special emphasis on public health and order benefitting the nations both economically and socially. All the elements of the objects clause of the TRIPS agreement need to go together harmoniously to enhance the meaning and the very essence of the entire agreement and the intent behind its formation. Thus in the opinion of the author, the responsibility lies on the member nations of TRIPS agreement to formulate their patent laws related to the pharma industry in such a way that both the rights of the pharmaceutical patent holders are protected and they derive the fruits of the labour they deserve along with improved access and affordability of medicines to the poor and developing countries especially for the life-threatening diseases because public health is a sector of vital importance as sound public health leads to the economic and social development of every nation as a whole leading to the achievement of a holistic public welfare concept. Section 3(d) can be taken as a good example by other nations of the world as a step towards striking this balance.

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