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# EVERGREENING OF PHARMACEUTICAL PRODUCTS AND RIGHT TO ACCESSIBLE MEDICINE: AN ANALYSIS IN INDIAN PERSPECTIVE

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## Abstract

*Population explosion and deep-rooted poverty in India are the major problems that hinder economic growth and contribute to violation of human rights like right to health. The effect of globalization under the auspices of the WTO regime led to implementation of the TRIPS agreement throughout the world and India is not an exception to this. To make its Intellectual Property law in conformity with the TRIPS agreement, India had to amend the patent law to grant product patents on pharmaceutical products. Multinational corporations taking advantage of TRIPS agreement resorted to patenting of life saving drugs which led to hike in prices of the life-saving medicines. Due to exorbitant prices those medicines became inaccessible to the poverty-stricken population in India which amounts to violation of right to health. To add insult to the injury, in order to perpetuate monopoly marketing rights on patented drugs, multinational corporations adopted the technique called evergreening of pharmaceutical products. So poor people can never get access to those drugs even after the expiry of the statutory period of twenty years. This being an issue directly connected to right to health, the discussion will focus on TRIPS agreement with special reference to product patent of pharmaceutical drugs in Indian perspectives, and give an understanding of evergreening of pharmaceutical products and legislative mechanisms to tackle its adverse effects to promote the right to health of the poor in India.*

**Keywords:** *Evergreening, TRIPS, Patent, Pharmaceutical drugs, Monopoly, Poor, right to health.*

## 1. Introduction

The 21st century world community has witnessed tremendous growth in industrial, scientific and technological development. Simultaneously it has faced problems like air, water and environmental pollution as well as various kinds of known, unknown, infectious and life-threatening diseases. Moreover, changes in their lifestyle have made human beings more prone to sickness with various kinds of complicated and newly emerged diseases. Health issues become a challenge for the entire world and covid-19 pandemic has made us fully aware of this. The issue is more challenging for India because of its rapidly increasing population, a major portion of which is living below the poverty line and suffers from life threatening diseases without adequate treatment or undergo substandard treatment. Though there exists Union and State Government initiated free Health Care measures, these are not adequate enough to cover the health care needs of the entire poverty-stricken population. The inadequate provision for free healthcare facilities in relation to its demand led to mushroom growth of private health care institutes but those institutes were mostly located in urban areas. The situation manifests that the majority of the people in India, irrespective of their economic condition, are to spend their own money for getting healthcare services. However due to the exorbitant cost of private healthcare services, poor people find it most difficult to arrange for money for getting

necessary medical treatment. In many circumstances they suffer untreated and even die untreated for not being able to buy the required medicine the price of which is beyond the affordability of the patient.

Pharmaceutical drugs or medicines are the most important component of medical treatment or health care services. Exorbitant prices of life saving medicines beyond the affordability of poor people is the one of the causes of denial of health care services to the poor. The prices of medicines shoot up with the enforcement of the TRIPS agreement in India. Patenting of pharmaceutical products in compliance with the TRIPS agreement and consequential grant of exclusive monopoly rights to the producer of patented drugs is the reason for this hike in prices of patented drugs. What is alarming is that pharmaceutical companies, under the influence of insatiable greed of earning profit perpetually by controlling the price of patented drugs, devised a technique called evergreening of patented drugs, and thereby perpetuated its monopoly right even beyond the normal statutory period. This made the prices of medicine beyond the reach of the affordability of the common man, especially poor people. This is simply an instance of denial of the right to accessible medicine which puts the human rights, especially human right to health in grave danger.

In this backdrop the study will discuss TRIPS agreement with special reference to product patent of pharmaceutical drugs in Indian perspectives, and give an understanding of evergreening of pharmaceutical products and legislative mechanisms to tackle its adverse effects to promote the right to health of the poor in India.

## 2. TRIPS Agreement and Product Patents of Pharmaceutical Drugs

The international initiative to protect intellectual property rights started with the Berne and Paris Conventions and culminated in the TRIPS agreement. The TRIPS Agreement included provisions of the Berne and Paris Convention. so many call the TRIPS agreement as the Berne and Paris plus convention. Trade related intellectual property rights (TRIPS) agreement was primarily aimed at protection of rights of owners of intellectual property. This agreement was annexed to the agreement establishing the WTO in 1994. The inclusion of the intellectual property regime in the WTO system raised concern for the developing countries as it might interfere with development goals and access to medicine. The TRIPS agreement fixed the minimum standards for IP protection which is obligatory to be observed and enforced by all the members of WTO. Under this obligation WTO member must provide patent protection to a process like method of producing chemical ingredients for a medicine as well as to a product (e.g., Medicine) for 20 years from the date of submitting of patent application. The TRIPS regime ushered in the exclusive monopoly of marketing rights of patent holders in respect to patented drugs. This led to excessively high prices of patented medicines due to lack of competition. This in effect undermined the right to affordable and accessible medicine of those who due to their poverty cannot buy those highly priced medicine for their treatment.

However, the TRIPS agreement incorporated certain flexibilities for developing and least developed countries so that they may utilize TRIPS-compatible norms in a way that enables them to implement their own public policy, such as facilitating quick access to pharmaceutical products in the interest of public health. Those flexibilities allowed the countries to take policy measures to mitigate the adverse impact of stringent obligatory provisions of the TRIPS agreement. The relevant provisions of TRIPS agreement to address the issue of accessible and affordable medicine in poor countries are as under:

**Parallel imports**: Goods legitimately placed on another market may be imported without

permission of the right holder, as long as the patent holder's rights have expired.[1]

**Patentability criteria:** WTO members may develop their own criteria for novelty, inventive steps and industrial application.[2]

**General exceptions**: WTO members have the opportunity to provide for limited exceptions to the patent's exclusive rights. However, such exceptions should not unreasonably conflict with normal exploitation of the patent and unreasonably prejudice the legitimate interests of the patentee.[3]

The Regulatory Review Exception also permits the use of a patented invention before the pattern expires for the purpose of obtaining marketing approval of a generic product for commercialization once the patent expires.

**Compulsory licensing:** A non-voluntary license may be granted by a duly authorised administrative, Quasi-judicial or judicial body to a third party to utilise a patented invention without the consent of the patent holder, subject to the payment of adequate remuneration dependent on the circumstances of each case.[4]

**Compulsory licensing for export purpose**: bis additional protocol for WTO members that do not have pharmaceutical manufacturing capabilities.[5]

**Government use**: a government authority may decide to use a patent without the consent of the patent holder for public, non-commercial purposes, subject to the payment of adequate regularization in the circumstances of each case.

**Competition related provisions**: Members may adopt appropriate measures to prevent or remedy anti-competitive practices relating to IP. These include compulsory licenses issued on the basis of anti-competitive conduct and control of anti-competitive licensing.

While showing its solidarity to TRIPS flexibilities, the United Nations Committee on Economic, Social and Cultural Rights, in the year 2001, stated that the National and international IP regime must not undermine the human rights obligations of States. The United Nations General Assembly again in 2011 stressed the need for TRIPS flexibilities to facilitate measures for improving access to healthcare.[6]

## 3. Rationale Behind Grant of Product Patent of Pharmaceutical Drugs

The pharma Companies are ready to invest to engage researchers for invent medicines to cure a disease because it is not an easy task and it requires prolonged research as well as huge investment. One way to realise the fruit of such investment is by using exclusive monopoly and marketing rights of the invented medicine for a considerable period of time. This would remove competition in the market and enable the pharma company to keep the price of the medicine abnormally high to earn profit over their incurred investment. This is made possible through the mechanism of granting product patents of the invented medicine. The positive aspect of the mechanism of granting product patent is it acts as an incentive to the inventor of medicine and encourages the inventor to invent new effective medicines for incurable diseases. On the other hand, the product patent system unreasonably raises the price of the medicines so as to be out of the reach and affordability of poor people. Thus, the product patent system raises a tension between public right to health and private economic rights.

[1] Article 6 of TRIPS Agreement
[2] Article 27 of TRIPS Agreement
[3] Article 30 of TRIPS Agreement
[4] Article 31 of TRIPS Agreement
[5] Ibid
[6] Articles 8, 31(K), 40 of TRIPS Agreement

## 4. Indian Scenario Regarding Product Patent of Pharmaceutical Drugs

Patent rights in India got statutory recognition as early as in 1970 with the enactment of Indian Patent Act 1970. However, this law abolished product patents of pharmaceutical products, it only provided for process patents. So Indian pharmaceutical companies had no prohibition on producing and marketing generic versions of life saving drugs patented elsewhere. The production of generic medicine kept the price of drugs affordable for the poor. This facilitated accessibility of medicines to the poor people for their own treatment. This favourable state of affairs prevailed in India till 1994 and later extended to 2005.

As soon as TRIPS came into force in 1995 it became obligatory on the member states to grant product patents of invented medicines. However, India being a developing country got a relaxation from such obligation for a period of 10 years ending in the year 2005. So, to comply with TRIPS provisions the Indian legislature brought about several amendments to the Patent Act,1970 making it mandatory to grant product patents of pharmaceutical products. Indian Patent Act, 1970 was amended in 1999, 2002 and 2005. The amendments to the Patent Act, 1970 effective form January, 2005 brought about following changes:

a) Exclusive marketing rights (EMR) and mailbox application provision was introduced.

b) Term of patent extended for 20 years from filing date[7].

c) India became a member of two international treaties i.e., Paris Convention, 1998 and patent cooperation treaty, 1998.

d) The terms 'invention' and 'inventive step' were redefined.[8]

e) Microorganism was covered under patentable subject matter.[9]

(f) Deletion of licence of right provision from compulsory licence.

(g) Incorporation of research exemption[10].

(h) Product patent introduced for invention in food, medicine and other drug substances.

(i) Pre-grant opposition initiated only after publication of patent application.

(j) This Act excluded patenting of computer program per se[11]

(K) It is also modified to introduce significant enhancement in efficacy of the variant of existing compounds.[12]

## 5. Evergreening of Pharmaceutical Drugs

As the statutory period for exercising patent right is limited to 20 years so upon the expiry of such period any pharma company may produce generic versions of the patented medicine. This would bring about competition in the market and thereby reduce the price of the patented medicine so as to be accessible to the poor people. However, to avoid competition in the market and prolong the exclusive marketing right beyond the limited statutory period, the pharma companies have devised a technique called evergreening of patented drugs.

Here the question arises what does amount to evergreening of pharmaceutical products. In simple sense Evergreening of pharmaceutical products includes obtaining secondary patents of an existing patented drug by introducing certain

[7] Substitution of section 53 The Patent Act, 1970
[8] Section 2(l) (j) The Patents Act, 1970
[9] (Section 3 (j) The Patents Act, 1970
[10] (Section 107- A) The Patents Act, 1970
[11] Section 3 (K) The Patents Act, 1970
[12] Section 3D of The Patents Act, 1970

insignificant changes in its molecular structures, methods of manufacturing, crystalline forms, formulas, dosage forms, combinations and/or indications. It simply means secondary patenting on incremental innovation of an existing patented drug.

The idea that provision for product patents would encourage the Pharma Companies to produce new effective drugs for incurable diseases has been proved to be wrong. Instances suggest that drug producing companies, instead of being engaged in inventing new blockbuster medicines, embrace "evergreening" strategies to maximise the profits of existing near-to-expire patents. One should not forget that the patent system was envisaged with the noble aim, inter alia, to encourage new invention. But evergreening of patented products adopted by the pharmaceutical companies left them to be content with marketing existing patented drugs and devising means to perpetuate exclusive monopoly rights by obtaining secondary patent with respect to the said medicine. Pharmaceutical companies started giving more importance on evergreening of the patented product than on invention of new medicines because inventing a new medicine involves huge investment. Conversely, the evergreening strategy adopted by the pharmaceutical companies does not require much investment and research.

Due to evergreening or obtaining secondary patent, the patented drug does not come in the public domain even after expiry of statutory period. This prevents market-driven competition on price of patented drugs so the price of the drug remains unreasonably high and beyond the reach of the poor people for an indefinite period. This state of affairs impels one to draw inferences that the mechanism of evergreening of pharmaceutical products on the one hand discourages a new invention and on the other hand tends to violate the right to accessible medicine.

## 6. Anti-Evergreening Legislative Provision

In India, for obtaining a patent the requisite conditions are i) Novelty, ii) Inventive step, and iii) Industrial Applicability. By defining non-patentable subject matter, the Indian Patent Law sets further limitations on the patentability of inventions.[13] According to this, an invention must not only be new, inventive, and useful in industry for it to be patentable, but it must also abide by all non-patentability rules.[14] Indian Patents Act suggests inventions that do not boost the effectiveness of a known substance but merely lead to the discovery of a new form of that substance are not patentable.[15]

**Bar of patentability**: "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 or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

**Explanation.** -For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy," from patentability.[16]

There are four categories of inventions that are not patentable i.e.,

(a) "mere discovery of a new form of a known substance,"

[13] Section 3 of The Patents Act, 1970

[14] Ibid.

[15] Section 3(d) of The Patents Act, 1970

[16] Ibid.

(b) "mere discovery of any new property for a known substance,

(c) "mere discovery of new use of a known substance," and

(d) "mere use of a known process, machine, or apparatus."

Any invention falling within the ambit of any of the above categories is considered non-patentable. Thus, the Patents Act, categorically mandates that i) a new form of a known substance, ii) a new property of a known substance, and iii) a new use of a known substance is not patentable without establishing enhancement of efficacy. The section further annexed an explanation regarding the different forms of a known substance such as isomers, salts, ethers, etc. The explanation clarified that such forms of known substances are patentable if they "differ significantly in properties with regard to efficacy." What creates controversy is that the Act does not define the terms like "efficacy", "properties" and "derivatives".

Unless enhanced or improved efficacy is established, minor modification in the already existing patented product is not further patentable. In ***Novartis AG v. Union of India and others***[17] the Supreme Court of India had to deal with the term "efficacy". The Court in this case stated the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Thus, in the matter of inventions directed towards a new form of a known drug or medicine, the function or utility of any drug is to cure a disease.

The Court in the *Novartis case*[18] stated:

> Mere demonstration of enhanced bioavailability property of the new form of the drug is not sufficient to satisfy the "efficacy" parameter of the Section 3(d) of the Patents Act. Only such properties that directly relate to efficacy can be considered. The Supreme Court further stated that whether or not an increase in bioavailability leads to an enhancement of efficacy in any given case must be specifically claimed and established by research data. Therefore, it was concluded that for any invention relating to, for instance, such as salts or different polymorphic forms of a drug, enhancement of "therapeutic efficacy" should be validated by the experimental data.[19]

## 7. Conclusion and Recommendations

Section 3(d) of the Patent Act, 1970 is an anti-evergreening provision that restricts patenting on incremental innovation and thus safeguards interests of the public by ensuring accessibility of life saving drugs to patients. This implies that Indian law does not support patenting for inventions which are minor modifications of the existing patented products and thereby prevents undue monopoly beyond the statutory period.

Right to accessible medicine is a public right. International as well as national legislative provisions impose obligation upon the states to ensure the right to accessible medicine to all citizens. Extensive and unrestricted patenting of pharmaceutical drugs creates a tension between public right to accessible medicine and private economic right to intellectual property. When conflict arises between these two rights, exclusive monopoly right to marketing the patented drugs must give way to right to accessible medicine. In this respect anti-evergreening legal provision i.e., section 3(d) of the Patent Act must be prudently used to restrict secondary patents of patented drugs for insignificant innovation.

[17] AIR 2013 SC 1311

[18] Ibid

[19] Id.

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