

# Patenting of Medicines: Access to Affordable Medicines in India

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## ABSTRACT

*This examination paper manages a worldwide wellbeing emergency is nearby. A huge number of individuals pass on every year from irresistible ailments that are treatable and preventable much of the time. The loss of life is unsuitably high in creating nations, where many kick the bucket since they don't approach viable and moderate drugs. People in general shock over the high costs of HIV/AIDS solutions has likewise raised open mindfulness on the issue of access to prescriptions and the part of licenses in expanding the costs of drugs. Licenses on pharmaceutical items and procedures furnish sedate organizations with restraining infrastructures over the generation and promoting of prescriptions, enabling them to settle costs at high rates to augment benefits.*

**KEYWORDS:** Patent, WHO, TRIPS, Affordable Medicines.

## INTRODUCTION

The rising costs of pharmaceuticals and the deplorability of a huge number of AIDS casualties in poor nations, who can't pay for the solutions they have to balance out the sickness, have excited boundless concern and put on the plan a level headed discussion on the for the most part high cost of these medications and drugs. The other essential issue under exchange is that of equivalent open doors for both created and creating nations to acquire the drugs that their populaces require to battle a scope of maladies, among which the AIDS scourge in sub-Saharan Africa constitutes a genuine catastrophe. The level headed discussion got another rent of life in November 2001, amid the Fourth World Trade Organization Ministerial Conference held in Doha (Qatar). There the privilege of nations to take measures to ensure general wellbeing and elevate access to meds was perceived. The WTO-TRIPS Agreement has gone under feedback for encouraging the expansion of these patent rights the world over. The commitment under TRIPS to execute exclusive expectations of licensed innovation assurance, including the 20-year insurance for patent rights and the commitment to perceive item and process licenses, will successfully take out rivalry from bland pharmaceutical makers and take into account expanded costs of prescriptions past the range of much more patients in the creating nations. Open feedback has been mounting, as are inquiries concerning the authenticity of licenses on life-sparing pharmaceuticals. This has prompted calls for changes or correction to the Agreement, which many feel is too vigorously for private rights and business interests, and against open interests. The procedure in the WTO TRIPS Council to have unique talks on TRIPS and Public Health gives a chance to WTO Members to consider the methods for tending to the negative effects of the TRIPS Agreement on general wellbeing and access to medications. A large number of individuals kick the bucket every year from irresistible sicknesses that are treatable and preventable much of the time. The loss of life is inadmissibly high in creating nations, where many pass on in light of the fact that they don't approach viable and reasonable medications. People in general shock over the high costs of HIV/AIDS meds has likewise raised open mindfulness on the issue of access to medications and the part of licenses in expanding the costs of drugs.

### Objective

- To find out about the wellbeing emergency in the creating nations.
- To investigate snags In the Use of Compulsory licenses And parallel Importation.
- To take in the significance of TRIPS understanding.

### HEALTH CRISIS IN DEVELOPING COUNTRIES AND THE TRIPS AGREEMENT AND PATENTS ON DRUGS

Around 14 million individuals kick the bucket every year from irresistible sicknesses, a large number of which preventable or treatable, for example, intense respiratory contaminations, diarrheal ailments, jungle fever and tuberculosis. Up to 45% of passings in Africa and Southeast Asia are believed to be because of an irresistible sickness. The loss of life is unsuitably high in creating nations, even as wellbeing pointers demonstrate changes in numerous nations of the world. This wellbeing emergency is caused by a few between connected elements - destitution, absence of access to wellbeing administrations, water and sanitation being some of them. Nonetheless, an imperative factor in the advancement of general wellbeing - and frequently, an immeasurably significant issue - is the supply of powerful and moderate prescriptions and people groups' entrance to such solutions and medicines.

On account of HIV, a human catastrophe of brain boggling measurements is currently within reach. Of the 36 million individuals with HIV on the planet, 25 million of them are in sub-Saharan Africa. In certain

African nations, more than a fourth of the grown-up populace has HIV, and future is anticipated to decrease drastically in the following ten years. For instance, future in South Africa is anticipated to fall by 20 years by the year 2010 because of the spread of HIV. The HIV scourge has put the focus on the issue of moderateness of basic prescriptions. In industrialized nations, AIDS passings have been significantly decreased incompletely in light of the accessibility of life-sparing medications. In any case, a year of the standard treatment of three-antiretroviral mix is evaluated at US\$10,000-15,000 . This value level puts such treatment far from a great many people in the creating scene, where 95% of the general population with HIV are from creating or immature nations. Open intrigue worldwide has been stimulated by the wellbeing emergencies in the creating nations, caused by the extravagant costs of medication medicines. HIV pharmaceuticals are a prominent illustration, yet there are likewise many instances of solutions for other dangerous maladies being made excessively expensive, just on the grounds that organizations owning or controlling licenses on the drugs have possessed the capacity to piece rivalry from different firms and different items. Costs of licensed drugs are particularly connected to the imposing business models delighted in by pharmaceutical organizations, ensured and kept up by patent rights.

### **The Trips Agreement and Patents on Drugs**

Patent rights are being extended around the world through the provisions of the WTO Agreement on TRIPS. Proponents of the TRIPS Agreement argue that patents and other intellectual property rights are essential for promoting research and development (R&D), as well as, stimulating innovation. Yet, there has been scant evidence that the introduction of TRIPS-compliant standards of IPR protection has promoted transfer of technology, R&D, or innovation in developing countries.

The intensive use of the patent system by corporations is intended to protect their competitive edge and markets, by keeping out their competitors. This strategic use of the patent system has the effect of stifling R&D, preventing innovation and restricting information flows in the developing countries. Patent protection is sought to be justified on grounds that the negative effect of monopoly rights will be outweighed by the incentive for creative activity, innovation and research and development. This trade-off is beginning to be questioned because the price and competition costs of strict patent protection have been very high. In the health and pharmaceuticals sector, this trade-off often comes with life or death consequences.

The implementation of the TRIPS Agreement will give rise to factors that can put access to medicines out of reach for millions of people in the developing world. The TRIPS Agreement obliges WTO Members to adopt and enforce high standards of intellectual property rights protection, which were derived from the standards used in developed countries. Conforming to TRIPS - by recognising and strengthening protection of intellectual property rights over pharmaceutical products and processes - will cause problems for developing countries. Implementation of the TRIPS Agreement may lead to high drug prices, low access to medicines and a weakening of pharmaceutical industries in the developing countries. It is feared that patent protection for pharmaceutical products and processes will have the effect of reducing or eliminating competition from generic production of medicines. There are about 10 industrialised countries with the pharmaceutical industry and research base, capable of developing new chemical entities or new medicines. The multinational drug companies in these countries own most of the pharmaceutical technologies and products through patents. The minimum term of 20-year patent protection required by TRIPS effectively allows a pharmaceutical company a monopoly over the production, marketing and pricing of patent protected medicines. By virtue of TRIPS protection, no generic equivalent can come into the market until expiry of the 20 years, denying patients cheaper alternatives.

Domestic manufacturing of pharmaceutical products in developing countries will come to a standstill. Developing countries are able to produce new medicines by a process of reverse engineering; that is, researchers in developing countries may develop a new process different from the process invented (and protected by patent) to manufacture the new medicine or chemical entity. Reverse engineering is possible only in countries where the patent law protects processes but not products. The TRIPS Agreement extends the scope of patent protection to both products and processes. It would therefore be possible to apply for patent rights over products for 20 years, and thereafter, further periods of 20 years each could be applied for products covered by patented processes. Some experts also caution that the 20-year protection can also be abused to extend the monopoly through process patents as well as patents on usage form, dosage form and combination form. In the US for example, patents have been taken on new combinations of drugs even when the product patent on the basic drug - the active ingredient - has long expired. Monopoly protection would be extended through minor changes to the existing medicines where the product patents have expired. Developing country pharmaceutical producers will find themselves pushed out of the market,

having to compete with the large MNCs. For the smaller producers in the developing world, which specialise and depend on manufacturing cheaper generic alternatives, this would no longer be possible - at least, until the expiry of the 20-year period. In some developing countries, domestic production capacity may never be developed. The TRIPS Agreement further requires patents to be granted, regardless whether the products are imported or locally produced. The means that patent holders can merely import their product, without having to work the patent in the country granting the right. This will mean that a MNC can supply global markets under the patent monopoly, exporting the finished product instead of transferring technology or making foreign direct investment. This rubbishes the argument of TRIPS proponents that strict patent regimes will increase the flow of technology and investment into developing countries.

Civil society groups and NGOs have called for amendment of the TRIPS Agreement so as to ensure a proper balance between the protection of private rights and corporate interests, and the promotion of public interests in socio-economic, technological development of member countries, including that of public health. Public criticism is mounting, as are questions about the legitimacy of patents on life saving drugs and the global monopolies provided to pharmaceutical companies by such patents. There is increasing public opinion that the present model for intellectual property rights protection advocated by TRIPS is too heavily tilted in favour of private right holders and against the public interest. The public outrage over HIV/AIDS medicines has added fuel to the negative public perception about the IPR system and about the role of TRIPS. All this is leading to a crisis of legitimacy for TRIPS. In the 6 years since its coming into force, there has been increasing evidence of many social and economic problems caused by the introduction of stricter intellectual property rights, as a result of the implementation of the TRIPS obligations.

#### **TRIPS AGREEMENT AND ACCESS TO MEDICINE**

For various creating nations, the elucidation and usage of the TRIPS Agreement requires assets and limit in overabundance of those effectively existing. Execution of the TRIPS Agreement speaks to an exceptionally noteworthy expansion in extension and term of patent insurance for creating nations, a significant number of which had not until now gave patent assurance to pharmaceutical items. Specialists from creating and created nations fear significant increments in sedate costs in the nations that had not allowed such licenses previously. Two of the most imperative measures incorporate the privilege of government to give mandatory licenses and the utilization of the rule of weariness of protected innovation rights, which considers parallel importation of licensed items. There are other essential exemptions to patent rights accommodated in the TRIPS Agreement, including special cases for trial utilize which are significant in the dialog on pharmaceutical items. This piece of the paper concentrates on the utilization of necessary authorizing and parallel importation measures.

#### **Compulsory Licensing**

The basic approach of the patents law is to strike a balance between the interests of associate creator of the customers and to make sure that the advantages of the new technological developments reach the people, and not exploited by the creator alone for the monopoly management. Required licensing allows a government to issue a licence to a 3rd party, whether or not a personal company or federal agency, for the proper to use or exploit a patent while not the patent holder's consent. Required licensees usually compensate the patent holder through payment of remuneration. Several developed countries build accessible some sorts of required licences, either in their patent laws or below the particular sector legislation. Such licences are considered an important component in their patent laws and are mechanisms wont to promote competition and stop abuse of patent rights and monopolies. The mere existence of a legal provision could also be enough to steer patent holders on the requirement to act fairly in cases of requests for voluntary licenses, while strengthening the negotiation position of potential licensees. Within the context of pharmaceutical patents, such licences represent a vital tool to push competition and increase the affordability of medication, while not depriving the patent holder of affordable compensation.

With a read to securing the objects of the jurisprudence system, the Controller has the facility to grant anyone interested UN agency has created associate application, a required licence upon such terms as he might view work, if glad that:

1. The affordable necessities of the general public haven't been glad, or
2. The proprietary invention isn't worked within the country, or
3. That it's not accessible to the general public at a fairly cheap value.

#### **Parallel Imports**

Parallel imports include the import and resale in a nation, without the assent of the patent holder, of a licensed item that was put available of the sending out nation by the patent holder. The hidden idea for parallel imports depends on the rule of weariness of rights. This standard is prefaced on the way that where the patent holder has been remunerated through the principal deal or appropriation of the item, he/she

never again has the privilege to control the utilization or resale of the item. It would likewise be in accordance with WTO's exchange advancement target that from the minute an item is advertised, the patent holder can never again control its resulting course. Nothing in the TRIPS Agreement disallows parallel importation. In particular, Article 6 permits every part nation the opportunity to fuse the rule of worldwide fatigue of rights - the fundamental legitimization for parallel imports - in its national enactment. It additionally expresses that Members are not subject to the WTO question settlement framework for debate identifying with depletion of rights. Deterrents In The Use of Compulsory Licenses And Parallel Importation It is crucial that the privilege of governments to utilize mandatory licenses and parallel importation measures are maintained and regarded. Such measures should likewise be fit for compelling usage. These TRIPS arrangements are combined with various conditions, making them hard to operationalise viably and quickly. All the more altogether, in spite of the fact that the TRIPS Agreement takes into consideration these measures to be embraced for the security of general wellbeing, some created nations have tried to give a tight understanding of the arrangements identifying with mandatory licenses and parallel imports, with the reason for limiting of extent of such measures. This circumstance has prompted the recognition that there is an absence of lawful clearness or basic comprehension of the TRIPS arrangements. This circumstance has prompted some unease and vulnerability with respect to creating nation Members, who are presently reluctant, or feel surrounded in their capacity, to attempt such measures in their national enactment.

### **Indian Scenario**

A portion of the changes to the Patents Act required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have recently been received by Parliament. Among the many issues managed by the changes, a standout amongst the most bantered about inquiries has been their effect in the wellbeing area and all the more particularly on access to medicines. The open deliberations are probably not going to die down with the reception of the Bill. From one perspective, the revisions have just been assaulted for not going sufficiently far to permit consistence with the TRIPS Agreement. Then again, the corrections are in a general sense changing the 1970 Patents Act and are probably going to adversely influence individuals' entrance to medicines.

### **CONCLUSION**

The extending wellbeing emergency in many creating nations has raised open worry about the absence of access of needy individuals to moderate solutions. Open shock over the excessive costs of HIV/AIDS drugs has additionally put the focus on the negative impacts of worldwide patent principles on the cost and moderateness of basic and essentially required prescriptions. Every year around 11 million individuals bite the dust from preventable irresistible illnesses. The AIDS scourge is asserting a great many lives, to the degree that in a few nations over a fourth of the populace is influenced.

Around the globe, open concern is mounting at how the presentation of strict patent administrations in creating nations required by the WTO's TRIPS Agreement is making the cost of licensed medications be set at high, regularly over the top levels. The viable restraining infrastructures conceded by TRIPS enable pharmaceutical monsters to smother rivalry from elective, minimal effort makers and to charge costs far above what is sensible. This is done to the detriment of numerous normal purchasers who are excessively poor, making it impossible to manage the cost of treatment.

Prior to the foundation of the TRIPS Agreement in 1994, nations were enabled more alternatives to reject divisions from patent standards in their national laws. Around 50 nations (both created and creating) avoided pharmaceutical items from licensing. Be that as it may, with the execution of the TRIPS Agreement, part nations are never again permitted. The Agreement allows part nations to take compensatory measures to counter the compelling restraining infrastructures of organizations owning licenses. Two of the most vital measures are the issuing of necessary licenses, whereby a legislature can offer consent to different gatherings to deliver or import items on which licenses had been given without the authorization of the patent holder, and the act of parallel imports. Since TRIPS does not restrain the grounds on which obligatory licenses can be given, a nation ought not be kept from issuing mandatory licenses on different grounds that it might consider important to meet general wellbeing and other open intrigue destinations.

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