



# INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

## THE IMPACT OF TRIPS ON ACCESS TO MEDICINES IN DEVELOPING COUNTRIES.

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### Abstract

Since its 1994 signing, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement has significantly influenced the development of the world's patent system. TRIPS implementation, however, has been a contentious topic, particularly in underdeveloped nations where obtaining affordable medications continues to be difficult. This paper examines the impact of TRIPS Agreement (Trade Related Intellectual Property Rights) in relation to developing countries. There has been a great deal of discussion and worry about how Trade-Related Aspects of Intellectual Property Rights (TRIPS) affect access to medications in developing nations. This paper will explore the research already in existence and examine how TRIPS has affected access to medication in developing nations. The study explores how parallel importing, compulsory licencing, and patent protection are affected by TRIPS. While it has made it easier for generic medications to enter the market, it has also made it more challenging for developing nations to use parallel importation and compulsory licencing to increase access to medications. In order to guarantee access to medicines in underdeveloped nations, authorities should investigate alternative methods like differential pricing and technology transfer.

**Keywords:** Developing, TRIPS, Medicines, Patents.

### Introduction

The World Trade Organisation (WTO) created the TRIPS agreement (Trade-Related Aspects of Intellectual Property Rights) in 1995 to safeguard intellectual property rights throughout the world. The TRIPS agreement includes a variety of topics, including patents, which have a substantial impact on developing nations' access to life-saving medications. Many developing nations had lax patent protection laws prior to the TRIPS agreement, which allowed them to produce generic versions of patented medications and

provide their populations with affordable healthcare. However, the TRIPS agreement required signatory nations to enact patent protection laws that complied with global norms, including those for pharmaceutical products.

This raised questions about how the TRIPS agreement might affect developing nations access to necessary medications because it may restrict their capacity to import or create generic versions of patented medications, increasing their cost and putting them out of the reach of many people. There has been considerable discussion and disagreement around the effect of the TRIPS agreement on access to medications in poor nations. The relationship between TRIPS and health has come to light as a result of the AIDS pandemic in Africa and mounting proof of the harmful effects of patents on the poor's access to medications. With more than 30 million HIV-positive individuals worldwide, the majority of whom reside in the most underdeveloped nations, addressing the issue of access to patented medications has become a top priority. While it is true that other factors, such as infrastructure and professional support, play an important role in determining access to drugs, as claimed by the pharmaceutical industry<sup>3</sup>, it is also true that prices brought on by the existence of patents ultimately determine how many people will die from AIDS and other diseases in the years to come.

### **Barriers to Accessing Medicines in Developing Countries.**

The World Trade Organisation (WTO) established the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement to safeguard intellectual property rights, such as patents, trademarks, and copyrights. The accord has drawn criticism, though, because of how it can affect underdeveloped nation's ability to get pharmaceuticals.

In developing nations, the TRIPS agreement has created the following obstacles to getting medications:

**Patents:** According to the TRIPS agreement, WTO members must grant patents on pharmaceutical items, which may drive up drug prices and restrict access to less expensive generic alternatives. This has been particularly difficult for poorer nations where many individuals lack the financial means to purchase pricey name-brand medications.

**Data exclusivity:** It is another provision of the TRIP'S agreement that forbids generic medication producers from using brand-name medicine safety and efficacy data to get regulatory approval for their own products. This may cause the release of less expensive generic medications to be delayed.

**Patent linkage:** Some nations have put in place patent linkage, which ties the approval of generic medications to the brand-name medication's level of patent protection. This may cause a further delay in the approval of generic medications.

**Enforcement:** As a result of the TRIPS agreement, nations who are WTO members must uphold intellectual property rights, which may result in legal disputes and litigation against generic medication producers. This may make it more challenging for generic drug producers to create and deliver cost-effective medications.

In general, the TRIPS agreement has come under fire for perhaps restricting developing nations' access to affordable medications. However, there are ongoing initiatives to lessen these obstacles, including the use of adaptabilities permitted by the agreement like parallel import and compulsory licencing.

### **Potential Solutions to Improve Access to Essential Medicines in Developing Countries.**

The Doha Declaration on the TRIPS Agreement and Public Health was adopted at the Fourth WTO Ministerial Conference (9–14 November 2001), at the initiative of developing nations, and it reflects the concerns expressed over the TRIPS Agreement's potential effects on public health. The Doha Declaration acknowledges the "gravity" of the public health issues that plague many poor and least developed nations, particularly - but not exclusively - those brought on by epidemics like HIV/AIDS, TB, malaria, and others. The TRIPS Agreement's effects on public health in general, without respect to specific diseases, are a concern for developing and least developed nations, which are reflected in the Declaration.

Although the Declaration expressly acknowledges the importance of intellectual property protection "for the development of new medicines," it also expresses concern about how it might affect prices. The Declaration states in paragraph 4 that the TRIPS Agreement should be construed to mean that members may take actions to protect the public health without being hindered from doing so:

We concur that the TRIPS Agreement should not forbid members from adopting actions to safeguard the public's health. Considering this, while reaffirming our commitment to the TRIPS Agreement, we assert that the Agreement may and should be interpreted and applied in a way that supports the rights of WTO members to protect public health and, specifically, to encourage access to medicines for everyone.

In this regard, we confirm that WTO members have the freedom to fully apply the TRIPS Agreement's flexible provisions possible.

A diversified strategy is necessary to address the challenging problem of increasing access to important medications in developing nations. Here are some suggested remedies that might be useful:

**Increase healthcare funding:** Developing nations frequently lack the resources necessary to deliver quality healthcare, particularly crucial medications. Increasing healthcare funding, whether through public spending or outside aid, is one solution.

**Improve supply chain management:** Inefficient supply chain management is a problem in many developing nations, which can result in shortages of critical medications. Enhancing supply chain management may make it possible to guarantee that medications are accessible when and where they are required.

**Reduce trade obstacles:** Many people in underdeveloped nations may not be able to afford necessary medications due to high tariffs and other trade restrictions. Medicines may become more affordable and accessible if these obstacles are removed.

**Encourage local production:** By promoting local production, developing nations can lessen their reliance on imported medicines. This can lead to the creation of jobs and ensuring that even in rural places, important medications are accessible.

**Gain more knowledge:** Many people in developing nations are unaware of the significance of essential medications or how to get access to them. Increasing awareness through public relations efforts and community involvement could aid in ensuring that individuals are aware of how to get the medications they require.

**Put price limits in place:** Governments can implement price controls to make sure that everyone can afford vital medications. By doing this, it may be possible to prevent individuals from having to decide between purchasing essentials like food and housing and medicines.

**Improve intellectual property rules:** By restricting the production of generic equivalents, intellectual property regulations can restrict access to necessary medications. Developing nations might work to strengthen their intellectual property rules to guarantee that necessary medications are accessible at reasonable costs.

**Encourage collaborations:** To solve the issue of access to vital medications, public-private partnerships can assist in bringing together governments, pharmaceutical companies, and other stakeholders. Together, these organisations can create original ideas that expand access to vital medications.

Overall, governments, international organisations, the private sector, and local communities must work together to improve access to important medications in developing nations.

#### Compulsory licences for export of medicines

The Doha Declaration lists "the right to grant compulsory licences" as one of the flexibilities. Without the patent holder's permission, a government agency or a court may grant a forced licence to use a patented innovation in a specific way. The TRIPS Agreement recognises this method as a legal option or flexibility, and some WTO members have adopted it in the pharmaceutical industry. It is normally present in most patent laws. The original TRIPS regulations, however, limited mandatory licences to primarily serving the local market, unless they were provided to address anti-competitive behaviour.

The Doha Declaration acknowledged that this constraint on compulsory licencing would prevent nations with little or no pharmaceutical manufacturing capacity from using it effectively. By adding a new type of compulsory licencing that didn't previously exist—one that is specifically designed for the export of pharmaceuticals to developing nations—the TRIPS Agreement amendment seeks to solve this problem. This new type of compulsory licence is referred to as a "trade related" compulsory licence. Because it had its beginnings in the Doha Declaration, this mechanism was occasionally referred to as the "paragraph 6 system."

The new Article 31 of the TRIPS Agreement provides this system full legal effect and permits the production and export of low-cost generic medications under a mandatory licence solely for the purpose of meeting the needs of nations who are unable to produce those items themselves. An interim waiver will continue to be in effect for the small number of WTO members who have not yet agreed to the change.

Parallel Universe

Parallel importing is also possible. This occurs when a product that the patent holder sells more affordably in one nation is illegally imported into another. Laws in different countries may or may not permit parallel imports. The Doha Declaration on TRIPS and Public Health stated that this means that countries are allowed to establish their own regulations and processes dealing with parallel imports. The TRIPS Agreement says that governments cannot pursue legal disputes on this topic before the WTO.

These options are flexible; they do not need to be used to make a difference. They are occasionally employed as a tool for haggling. For instance, the fear of a mandatory licence may induce a patent holder to lower the asking price.

## **RECOMMENDATION FOR POLICY MAKERS STAKEHOLDERS AND INTERNATIONAL ORGANIZATIONS**

It is a complicated problem that calls for a multi-stakeholder solution to increase access to important medications in underdeveloped nations while preserving intellectual property rights. Following are some suggestions for decision-makers, interested parties, and international organisations:

Encourage the use of the flexibility provided by international accords on intellectual property: Countries can encourage access to vital medications by utilising the legal flexibility given by international accords like the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Compulsory licencing, parallel imports, and government usage licences are a few of these flexibilities.

financing for research and development should be raised, especially for neglected diseases that impact developing nations. Public and private sector financing for research and development (R&D) of important medications should be enhanced. To promote innovation and information exchange, governments should also support open access to research data and publications.

Encourage technology transfer: It is important to encourage developing nations to establish their own pharmaceutical manufacturing capabilities and to enter into agreements with developed nations to transfer technology. This will facilitate greater access to medicines while lowering their price.

Strengthen regulatory frameworks: To guarantee the efficacy, safety, and quality of medicines, developing nations must have robust regulatory frameworks. International organisations can support the establishment of regulatory systems by offering technical assistance and capacity building.

**Boost accountability and transparency:** Governments and pharmaceutical companies should be open about their pricing practises and R&D expenditures. Additionally, any unfair practises that restrict access to necessary medications should be made accountable by them.

**Encourage voluntary licencing agreements:** Agreements between generic manufacturers and pharmaceutical corporations can help to improve access to necessary medications. Such agreements can be promoted by governments and international organisations.

**Encourage generic manufacturers to compete:** Policies that encourage competition among generic producers can aid in lowering the price of important medications. Governments can potentially bargain cheaper drug prices by buying in bulk and pooling purchases.

**Encourage the strengthening of the nation's health system:** The availability of vital medications is directly related to the health system's overall effectiveness. Investment in infrastructure, training of healthcare professionals, and other actions can help governments and foreign organisations assist the strengthening of the health system.

In conclusion, it takes a concerted effort from all stakeholders to promote access to important medications in developing nations while preserving intellectual property rights. The suggestions can be used as a springboard for policymakers, stakeholders, and international organisations to collaborate in order to guarantee that those who require vital medicines have access to them.

## CONCLUSION

There has been discussion on the effect of the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement on access to pharmaceuticals in developing countries for a number of years. The pact has come under fire for restricting access to affordable medicines in low- and middle-income nations, despite the fact that it was designed to safeguard intellectual property rights and encourage innovation.

On the one hand, the TRIPS agreement has made it easier for new medications to be developed and commercialised, which has greatly improved the way many diseases are treated. However, many people in developing nations, where the burden of disease is frequently highest, are unable to access patented medications due to their high costs.

In order to solve this problem, a number of steps have been implemented, such as the creation of generic medications and the usage of compulsory licencing. Without the permission of the patent owners, countries may grant licences to local manufacturers to create generic versions of patented medications under the terms of compulsory licencing. This has assisted in bringing down the price of medications in many poor nations.

In conclusion, the TRIPS agreement has a mixed record of effects on developing nations' access to medical care. It has sparked creativity and resulted in the creation of novel medications, but it has also restricted many people's accesses to affordable medications. To strike a balance between defending intellectual property rights and guaranteeing that vital medications are available and inexpensive for everyone who needs them, governments and international organisations must cooperate.

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