

# Is the TRIPS Agreement a double-edge sword?

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## **Abstract:**

Globally, the Agreement on trade-related aspects of intellectual property rights (TRIPS Agreement) is widely adopted as a prerequisite for World Trade Organisation (WTO) membership. This Agreement represents the first international benchmark for minimum intellectual property rights (IPRs) standards. It obliges the Member States to implement national laws that protect and enforce domestic IPRs, encompassing technology innovation, technology dissemination, access to healthcare, and biotechnology. However, the efficacy of the TRIPS Agreement in equitably benefiting all Member States, particularly those in the developing world, with regard to public health needs and healthcare access, remains questionable. Moreover, the TRIPS harmonisation project, a focal point in multilateral discussions, raises significant interest. Undoubtedly, the primary aim of this harmonisation is to enhance the efficiency, uniformity, and coherence of IPRs systems across Member States. Yet, the appropriateness of applying a 'one-size-fits-all' policy to nations at varying stages of development warrants scrutiny. This article employs the recent TRIPS Agreement provisions and comparative methodology to examine the fundamental impacts of the current TRIPS framework, alongside the practical benefits and challenges associated with its implementation.

**Keywords:** biotechnology, harmonisation, healthcare, intellectual property rights, technology.

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## **1. Introduction**

In the contemporary global market, we observe rapid advancements in the creation of intellectual properties, such as designs, inventions, and artistic works. Consequently, an effective framework for the protection of IPRs is essential, not only to deter infringements but also to facilitate the recovery of compensation for any resultant losses and damages. The inception of the TRIPS Agreement [1] signifies a milestone in safeguarding and enforcing IPRs for Member States of the WTO.

Moreover, the significant success of the TRIPS Agreement lies in its requirement for Members to adhere to specified minimum standards for intellectual property protection [2]. Consequently, over a hundred nations, encompassing both developed and developing countries, have implemented the TRIPS Agreement [3]. The integration of the TRIPS Agreement within the WTO's framework represents arguably the most extensive and ambitious endeavour to harmonise IPRs globally, aiming

to establish unprecedented international uniformity in this domain. Nevertheless, the impact of the TRIPS Agreement's harmonisation on countries at varying stages of development remains a contentious issue. This paper seeks to elucidate this matter by examining recent regulations and legal journals, thereby providing an overview of the principal effects and critical challenges posed by the TRIPS Agreement.

## **2. The Agreement on trade-related aspects of intellectual property rights**

### **2.1. Background**

To facilitate the reduction of international trade barriers and the promotion of high standards in intellectual property globally, the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) [4] uniquely introduced multilateral negotiations on "trade-related IPRs" [5]. In 1994, the emergence of the Agreement on TRIPS Agreement was acknowledged as a key achievement in the trade negotiations that spanned eight years [6].

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The Preamble to the TRIPS Agreement clearly expressed the goal to 'reduce distortions and impediments to international trade' between developed and developing countries worldwide. In order to achieve its objectives, the TRIPS Agreement asks the WTO Members to provide the minimum standards of protection in each sector. Specifically, these standards encompass what should be protected, the rights granted, allowable exceptions to those rights, and the minimum duration for which protection should be ensured.

More significantly, Article 8 of the TRIPS Agreement ends with the provision on two principles. Firstly, Members to 'adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement'. Secondly, the principle allows Member States to introduce "appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology". It can be seen that these principles have become a vital point of reference, which would allow domestic laws to address instances of dominant market position abuse or monopolistic practices by leading companies.

Unlike earlier IP conventions, the TRIPS Agreement attracted 160 WTO Member States, highlighting its global significance. Clearly, the TRIPS Agreement has set out minimum standards for the protection and enforcement of all significant IPRs, including copyrights, trademarks, and patents, under a single agreement [7].

## **2.2. The main effects of the Agreement on trade-related aspects of intellectual property rights**

The TRIPS Agreement has prompted WTO Members to enhance domestic protection of IPRs. It provides legal frameworks for all WTO Member States to formulate standards that align with their IPR requirements [8]. However, the impact of the TRIPS Agreement varies across different sectors and is influenced by each nation's level of development. This paper will delve into the main effects of the TRIPS Agreement in various sectors.

*Innovation of technology:* 'Protection' is regarded as central to the current international intellectual property system, compelling Member States to prioritise IPR

protection in national legislation [9]. Article 7 of the TRIPS Agreement, under its Objectives provision, identifies one of the goals of developing minimum standards for "the protection and enforcement of intellectual rights" as contributing to technological innovation [4]. In essence, the TRIPS Agreement prioritises technological advancement [7].

Most developing and least developed countries are seen to have limited scientific and technological capabilities [10], often due to inadequate facilities and underdeveloped infrastructure. Implementing the TRIPS Agreement in these States is likely to encourage technological innovation. Research indicates that robust IPR protections can attract more foreign direct investment [11]. Over 80% of pharmaceutical, chemical, and electrical equipment companies in industrialised nations like the United States and Japan consider the strength of IPR protection in a host country as a critical factor influencing investment decisions in research [12]. Recently, foreign direct investment in developing countries increased from 52.3 to 74.3% between 2020 and 2021 [13].

While foreign investment is not directly influenced by the TRIPS Agreement, it significantly impacts investment levels in a nation. Article 7 of the TRIPS Agreement underscores international investment protection by setting IPR protection standards [14]. These standards are seen as key elements considered by foreign investors when selecting locations for their manufacturing facilities.

*The dissemination of technology:* Article 7 of the TRIPS Agreement stipulates that "The protection and enforcement of IPRs should contribute to the transfer and dissemination of technology". It is incumbent upon developed states to promote and encourage technology transfer, technical cooperation, and legal assistance [15] to developing and least-developed nations to establish and develop "a sound and viable technological base" [4].

In practice, foreign investment and licensing are common methods for technology transfer between countries. For instance, Germany has exported solar panels and wind turbines to Pakistan [16], and Chinese investors have imported clean coal technology from the USA [17]. However, it is predominantly private companies, rather than developed countries, that effectively facilitate technology transfer. Some scholars argue that 'developed States are reluctant to transfer technology to developing and least-developed countries' [18], despite such transfer being a crucial prerequisite for these countries to build a technological foundation.

Presently, technology transfer tends to be conducted by small and medium-sized enterprises. By obtaining licensing for IPRs in new markets, such as developing or least-developed countries, these companies establish subsidiaries to introduce and transfer technology [19]. Yet, developed nations and multinational corporations tend to dominate licensing activities [20]. Specifically, only ten developing countries account for 91% of all cross-border technology license fees [21], and parent corporations and their international subsidiaries receive 70% of global royalties and license payments [20]. Although Article 66(2) outlines the responsibilities of developed countries concerning the transfer and dissemination of technology to developing and least-developed nations, some Member States limit their support to technical assistance in implementing the TRIPS Agreement, rather than actively encouraging technology transfer. Consequently, the TRIPS Agreement's impact on technology transfer faces challenges in bridging the technology gap.

*Access to health care:* Article 27(1) of the TRIPS Agreement mandates that all Member States grant patents for all inventions, "whether products or processes", in all technology sectors, including pharmaceutical patents. This requirement is highly controversial, as many pharmaceutical patents are directly linked to fundamental human rights, notably the right to life and the right to enjoy physical and mental health [22].

Prior to the TRIPS Agreement, both developing and developed States were reluctant to grant pharmaceutical patents, considering the health and developmental objectives of each nation [23]. The implementation of the TRIPS Agreement in developing countries' medical systems is likely to produce inconsistent effects. In some developing nations, the introduction of pharmaceutical patents could lead to exorbitant medicine prices, rendering them unaffordable for the majority of the population. Consequently, a primary concern for developing and least-developed countries is maintaining stable drug prices. For example, India, which experienced rapid expansion in its drug development sector from 1970, had some of the highest medicine prices among developing countries [24]. In response, India not only revoked protection for pharmaceutical patents but also regulated drug prices. Undoubtedly, by reducing pharmaceutical prices, India not only stimulated its local medical industry but also improved the health status of its population.

Additionally, a significant issue arises when pharmaceutical patents are protected: major pharmaceutical corporations such as Pfizer, Johnson & Johnson, and Moderna may consolidate power. Decisions regarding medicine costs will be controlled by these large corporations, impacting the developing world, particularly during health crises. Patent decisions over pharmaceuticals can have significant effects, especially when the world faces severe pandemics like COVID-19, Ebola, or HIV/AIDS.

Recognising the challenges in accessing healthcare in developing countries, Paragraph 6 of the Doha Declaration (2001) on the TRIPS Agreement and Public Health addressed this concern: "We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002" [25]. After two years of negotiation, the WTO General Council declared that the TRIPS Agreement should be implemented to protect public health and promote access to medicines for all. Consequently, "the obligations of an exporting Member under Article 31(f) and 31(h) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)..." [26]. Thus, countries with limited capacity to produce generic medicine can import medicines from other states without paying royalties, as the exporting country has already compensated for this [27]. This measure has partially resolved the issue of medicine access in developing countries. For example, while an individual in the USA might pay 15,000 to US \$20,000 annually for HIV/AIDS treatment using patented drugs, in South Africa, the cost is only \$88 per year for generic treatments [28].

*Biotechnology:* Article 27 of the TRIPS Agreement mandates that patents be available in all technological sectors. Unlike traditional techniques, biotechnology is a costly endeavour, requiring significant research investment and being vulnerable to duplication by competitors through reverse engineering. Therefore, enhancing IPRs in biotechnology is prioritised under the TRIPS Agreement to protect innovators against risks.

Developed-country Members are experiencing a rapid increase in biotechnology protection. For instance, in 1930, the United States was the first

country to protect asexually reproduced plant varieties [29]. In 1998, the United States Patent and Trademark Office (USPTO) issued patents for a mouse genetically altered to aid cancer research [27]. Although developed countries are striving to promote IPRs over biotechnological products, challenges exist. Ethically, some Member States' religions object to claiming ownership over living entities, leading these nations to develop intellectual property systems aligned with their religious values and beliefs. Environmentally, the effects of altering the genetic makeup of living organisms are largely unknown [19], necessitating careful regulation and testing of biotechnological innovations to prevent major environmental damage [19]. Consequently, the granting of biotechnology patents is a topic of ongoing debate and concern, with some arguing for delayed patent awards until a better understanding of the environmental consequences is achieved. Because of these reasons, the award of patent rights for biotechnological is raising concerns and discussions.

### **2.3. Some issues raised by the Agreement on trade-related aspects of intellectual property rights**

The TRIPS Agreement is not considered a static legal document, as the TRIPS negotiators have included several regulations within the Agreement to formulate a future work plan, termed a 'built-in agenda' [30]. Enforcing the TRIPS Agreement requires WTO Member States to enhance their review processes and comply strictly with the Agreement to maximise IPR protection. However, some Member States, particularly developing states, face challenges in ensuring that the TRIPS Agreement reflects and meets their socio-economic needs. Issues raised and discussed in the 'built-in agenda' include four core areas: Article 27.3(b) of the TRIPS Agreement, Geographical indications (GIs), Traditional knowledge (TK) and Folklore, and Non-violation complaints (NVC).

*Article 27.3(b) of the TRIPS Agreement:* Article 27.3(b) allows Member States the option to exclude patents on biological inventions related to 'plants and animals other than micro-organisms' and 'biological processes for the production of plants or animals other than non-biological and microbiological processes'. Yet, it also mandates Member States to 'provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof' [4]. As part of the 'built-in agenda', this subparagraph was subject to review four years after

the entry into force of the WTO Agreement. During the review process, the TRIPS Council collected information from Member States on their approaches to these issues in national intellectual property law. Two primary concerns raised by Members were: (1) The patentability of certain life forms and whether there should be exclusions for any such invention; and (2) How to strike a balance in the protection of plant varieties between private and community interests and other issues such as farmers' rights and maintaining biodiversity [30].

Additionally, controversies among Member States exist concerning biotechnology patents. This provision is seen as lacking harmonisation between the TRIPS Agreement and the Convention on Biological Diversity (CBD) [31], as well as in the linkages between patent protection and the facilitation of technology transfer. Firstly, there is debate over potential conflicts between the TRIPS Agreement and the CBD [32]. While the CBD includes exclusive provisions on bio-piracy and bio-trade [31], the TRIPS Agreement does not provide a legal framework for access rights. Moreover, not all WTO Members are parties to the CBD, leading to legal challenges in cases of bio-piracy infringement for those who are signatories to the TRIPS Agreement but not the CBD. Secondly, concerns arise regarding whether the transfer of biotechnology might inadvertently facilitate bio-piracy, given the TRIPS Agreement's objectives include technology transfer and dissemination. Nevertheless, it appears there is no direct conflict between the TRIPS Agreement and the CBD, as Member States can implement both Agreements in a mutually beneficial manner through domestic intellectual property legislation [32].

*Geographical indications:* Under the TRIPS Agreement, GI is defined as a sign used on goods "originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin" [4]. Examples include 'Champagne' from France and Jersey Royal potatoes, which received Protected Designation of Origin status in 1996 [33]. Although GIs are primarily used for food and drinks, the Doha Ministerial Declaration sparked debates about extending higher-level protection to other products. Currently, the TRIPS Agreement only provides protection for GIs for wines and spirits [4]. Some Member Nations, including the European Union, Switzerland, and several developing

nations, advocate for more extensive protection in this area, arguing that enhanced GI protection can help these nations oppose the ‘usurpation’ of geographical phrases [30]. Also, a GI extension will encourage localized production, thus contributing to the preservation of traditional cultures and boost national identity.

*Traditional knowledge and folklore:* The protection of TK and folklore was highlighted in the Doha Declaration in 2022 [34]. The international community is debating the necessity of actions to protect TK and folklore. Although traditional knowledge and folklore issues do not fit well into the overall picture presented in the Conference programme, an increasing number of Member States express concerns about this issue. Concerns include the inappropriate granting of patents or other IPRs to entities without legitimate rights to these TK and folklore and the unauthorised use of TK and folklore by those who did not generate them [35]. Despite being part of the ‘built-in agenda’, discussions on this issue have been somewhat limited. However, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional knowledge and Folklore (IGC) is developing legal mechanisms to protect these valuable global resources.

*Non-violation complaints:* Article 64.2 of the TRIPS Agreement initially imposed a five-year moratorium on NVC from the WTO Agreement’s entry into force. Article 64.3 tasked the Council of TRIPS with examining the scope and modalities for such complaints [4]. In practice, the moratorium on using NVC under the TRIPS Agreement has been extended several times by various Ministerial Conferences and the General Council in 2001, 2005, 2017, and 2019 [30].

There are ongoing debates among Member States regarding the applicability of NVC to the TRIPS Agreement. On the one hand, some members argue that NVC is a crucial part of the WTO dispute settlement system across all WTO agreements, playing a pivotal role in guaranteeing a balance of benefits during multilateral negotiations with WTO Members. They contend that the moratorium provision in the TRIPS Agreement should be removed. On the other hand, others believe that the TRIPS Agreement does not directly address issues of market access and tariffs. Consequently, incorporating NVC into the TRIPS Agreement system could potentially conflict with the general policies and goals of the national intellectual property system in each country [30].

### 3. The harmonising effects of the Agreement on trade-related aspects of intellectual property rights

Harmonisation has been a prevailing trend from the late nineteenth century through to the end of the twentieth century [36]. Through multilateral treaties such as the Paris Convention for the Protection of Industrial Property (the Paris Convention) in 1883 [37] and the Bern Convention for the Protection of Literary and Artistic Works (the Bern Convention) of 1886 [38], the movement for the harmonisation of IPRs is evident in both substantive and procedural aspects relating to creative works and industrial property. Particularly, the TRIPS Agreement has significantly influenced efforts to harmonise IPRs [39]. The TRIPS Agreement establishes global standards for the harmonisation of intellectual property, but these standards and procedures do not follow an ad hoc basis [40]. As a result, Member States, especially those from developing countries, may find it challenging to meet these international standards during the national adaptation process. While the implementation of the TRIPS Agreement has been ostensibly accepted by all WTO Members, there are ongoing complaints about the difficulty in meeting its requirements [41]. Debates persist over whether the harmonising effects of the TRIPS Agreement promote or hinder the sustainable development of Member States.

In practice, for development to be achieved, each nation should focus not only on boosting finances but also on increasing diversity and paying attention to the quality of achievements. Most IPR provisions focus on sustainable development, meaning that the TRIPS Agreement’s harmonisation reflects a process of cultural adaptation for each nation. Rules including copyright, patent, or trademark under the TRIPS Agreement influence the dissemination or transfer of technology between developing and developed countries. Its harmonisation impacts community control over the protection of TK and folklore, and access to essential drugs and pharmaceuticals [42]. The TRIPS Agreement’s efforts to narrow barriers and create new boundaries for the patent protection of life forms and biological materials are significant for both the developing and developed worlds. In a global context, some developing countries may apply the TRIPS Agreement based on their unique legal and cultural diversities, while considering public interests and overall community development [40].

However, in some cases, the TRIPS Agreement’s harmonisation can hinder sustainable development due to the lack of flexibility in its implementation in

developing states, limiting their freedom to customise IPR strategies to suit their national economies. The Doha Development Agenda highlights the role of global commerce in achieving sustainable development within the intellectual property system [43]. There are concerns that policy provisions on IPR offered by developed nations, which could affect rights, are prioritised in the development policies of developing and least-developed nations [44]. Consequently, instead of creating opportunities for these nations, the TRIPS Agreement's harmonisation can hinder development and exacerbate the challenges in adjusting and implementing the TRIPS Agreement in the developing world.

Unlike other WTO agreements, the TRIPS Agreement is the primary agreement harmonising IPRs, including trademarks, patents, copyrights, and trade secrets, and sets minimum standards. However, whether the TRIPS regime is effective depends not on vague terms such as 'adequate and effective,' 'fair and equitable,' as expressed in its objectives and purposes, but on its degree of acceptance in practice. To some extent, the TRIPS Agreement is also seen as a 'very mixed bag' [9], filled with numerous multilateral regulations to protect the international IPR system. Nevertheless, in the context of current unbalanced world economies, it would be significantly beneficial if the TRIPS regime were reformed to help "a country's IPR regime coevolve with its economy" [45] in response to changing global needs.

#### 4. Conclusions

All WTO Members, including both the developing and developed world, have accepted the TRIPS Agreement as a global policy to reduce "distortions and impediments to international trade", while "promoting effective and adequate protection of IPRs" [4]. In practice, the TRIPS Agreement is effectively playing its role in maintaining balance and bringing together the long-term interests of Member States.

However, there are still issues arising during the implementation of the TRIPS Agreement that Member States must confront and address, such as biotechnology, GI, and the protection of TK. Additionally, concerns remain about the effects of the TRIPS Agreement's harmonisation on the development of Member States. Evidently, the evolving global IPR system, akin to a "double-edged sword" [40], has both stimulating and hindering effects on society as a whole.

#### COMPETING INTERESTS

The author declares that there is no conflict of interest regarding the publication of this article.

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