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TRIPS Agreement and the experience of Kenya regarding patents and compulsory licensing of HIV/AIDS drugs

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DOI: <https://doi.org/10.2478/bjir-2024-0022>

Abstract

Although the TRIPS Agreement establishes minimum standards for the protection of intellectual property, it also leaves some room for policy interpretation by WTO members, whether they are developed or developing nations. This allows them to implement the Agreement's provisions in a variety of ways and to enact legislation in areas that are not covered by the Agreement's minimum standards. The Doha Declaration on TRIPS and Public Health specifically recognizes the importance of the implementation of TRIPS flexibilities for the design of a pro-competitive intellectual property system and, in particular, for achieving public health objectives. The paper draws general aspects of the TRIPS agreement, requirements to be part of the TRIPS agreement, implementation of patent protection, the DOHA declaration and lastly a case study regarding compulsory licensing of HIV/AIDS drugs.

Keywords: TRIPS agreement, intellectual property, standards, trademark.

1. Introduction

All of the World Trade Organization's members are bound by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (WTO). It specifies minimal requirements for national governments to follow when regulating various types of intellectual property (IP) with relation to citizens of other WTO member countries. The TRIPS agreement, which is overseen by the WTO, was negotiated at the conclusion of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) between 1989 and 1990 (Scherer, 2001). The TRIPS agreement, the most comprehensive multilateral agreement on intellectual property to date, was the first to integrate intellectual property law into the global trading system. Concerned that rich countries were insisting on an overly restrictive interpretation of TRIPS, developing nations started a round of negotiations in 2001 that resulted in the Doha Declaration (Kiri, 2023). The WTO's Doha declaration defines the scope of TRIPS, for instance by

declaring that it can and should be construed in light of the objective “to facilitate access to medicines for everyone.”

TRIPS mandates that WTO members provide copyright rights, which include those of authors and other copyright holders as well as those of holders of related rights, such as musicians, sound record producers, and broadcasting companies; geographical indications; industrial designs; integrated circuit layout-designs; patents; new plant varieties; trademarks; trade names; and undisclosed or confidential information. TRIPS also outlines methods for enforcing agreements, seeking redress, and resolving disputes. The promotion of technological innovation, the transfer of knowledge, and its dissemination are all goals that must be attained through the protection and enforcement of all intellectual property rights. This is done to the mutual benefit of those who produce and use technological knowledge, as well as in a way that promotes social and economic welfare and a balance of rights and obligations.

2. Central goals of the TRIPS agreement

Both principles and regulations are included in the TRIPS Agreement. Members acknowledge “the need for new rules and disciplines concerning the provision of adequate standards and principles concerning the availability, scope, and use of trade-related intellectual property rights” in the preamble to the TRIPS Agreement as well as “the need for a multilateral framework of principles, rules, and disciplines dealing with international trade in counterfeit goods.” In addition to the structural principles found in all WTO treaties, such as trade liberalization, non-discrimination, and special and differential treatment, these principles also exist.

Therefore, it would seem fortunate for the process of treaty interpretation that Members took pains to define a set of principles inside the operative area of the text in addition to the substantive rules of the Agreement. When a Member State decides to implement measures in accordance with those stated in Article 8, these principles are to be followed. This strategy would be similar to that used with respect to other provisions found in other WTO Agreements, like the General Agreement on Tariffs and Trade (GATT). The requirement for the socio-economic optimum of intellectual property legislation is acknowledged in Article 8 just like it is in Article 7. It implies that in order to safeguard and/or advance social and economic goals, intellectual property protection frequently necessitates interventionist action. Contrary to Article 7, however, Article 8 explicitly permits State Parties to take certain actions in support of a clear but broadly defined policy aim. The principles set forth in Article 8 make it easy to interpret and apply the Agreement’s substantive regulations. National regulatory autonomy, consistency, need, and reasonableness are the most important of these principles (Braga, Fink, 2001).

So overall, the of a GATT intellectual property agreement would be to lessen the distortions and barriers to lawful trade in goods and services brought on by insufficient levels of intellectual property protection and enforcement. All parties should concur to conduct the following actions in order to achieve that goal:

1. Deploy border controls to effectively economic dissuade the international commerce of goods and services that violate intellectual property rights;
2. Recognize and put into practice rules and norms that give suitable tools for acquiring and protecting intellectual property rights and a foundation for their effective enforcement;
3. Make sure that any actions taken to safeguard intellectual property or uphold intellectual property rights don't hinder legal trade;
4. Extension of international notice, consultation, monitoring, and conflict resolution processes to intellectual property protection and enforcement.

3. Requirements to be part of the TRIPS agreement

Undisclosed information, such as trade secrets or know-how, must be protected in accordance with the TRIPS Agreement. Article 39.2 states that information that is secret, has commercial value because it is secret, and has been subject to reasonable efforts to keep it secret must be covered by the protection. The Agreement does not require that undisclosed information be treated as property, but it does stipulate that whoever is lawfully in control of such information must be able to prevent it from being disclosed to, acquired by, or used by others without that person's consent in a way that is inconsistent with fair business practices (Bermudez, Epsztejn, Oliveira, and Hasenclever, 2000).

The Agreement also includes clauses on unreleased test results and other data that must be submitted before governments will approve the marketing of medicinal or agricultural chemical goods that contain new chemical entities. In this case, the relevant Member government is required to safeguard the data from improper commercial usage. Additionally, Members are required to keep such information private, save in cases of public safety or unless efforts are made to shield it from improper commercial usage.

Requirements to be part of the TRIPS agreement include (Sihanya, 2005):¹

- Copyright terms must extend at least 50 years, unless based on the life of the author (Art. 12 and 14);
- Copyright must be granted automatically, and not based upon any "formality". Computer programs must be regarded as "literary works" under copyright law and receive the same terms of protection;
- National exceptions to copyright (such as "fair use" in the United States) are constrained by the Berne three step test;
- Patents must be granted for "inventions" in all "fields of technology" provided they meet all other patentability requirements (although exceptions for certain public interests are allowed (Art. 27.2 and 27.3) and must be enforceable for at least 20 years (Art 33);
- Exceptions to exclusive rights must be limited, provided that a normal exploita-

¹ "TRIPS Agreement (as amended on 23 January 2017)". Wto.org. Archived from the original on 18 October 2020. Retrieved 12 February 2021.

tion of the work (Art. 13) and normal exploitation of the patent (Art 30) is not in conflict;

- No unreasonable prejudice to the legitimate interests of the right holders of computer programs and patents is allowed;
- Legitimate interests of third parties have to be taken into account by patent rights (Art 30);
- In each state, intellectual property laws may not offer any benefits to local citizens which are not available to citizens of other TRIPS signatories under the principle of national treatment.

4. Implementation of Patent Protection in the TRIPs Agreement and Post Trip agreement

All member states are subject to the same requirements under TRIPS; however, developing nations were given more time to enact the necessary modifications to their national legislation, in two levels of transition in accordance with their level of development. For developing nations, the transitional period ended in 2005. The implementation transition time for TRIPS for least developed nations was extended to 2013 and for pharmaceutical patents until 1 January 2016, with the possibility of an additional extension.

Therefore, it has been argued that the TRIPS norm, which calls for all nations to have stringent intellectual property laws, will be harmful to the development of less developed nations. It has been suggested that using the TRIPS' flexibility to enact the most IP rules is, at least on the surface, in the strategic interests of the majority of developing countries, if not all of them (Stasa and Dedej 2023).

Most of the time, this hasn't happened. According to a 2005 WHO report, many developing nations have not fully incorporated the TRIPS flexibilities—compulsory licensing, parallel importation, restrictions on data protection, use of broad research, and other exceptions to patentability, among others—into their legal systems as permitted by the Doha Agreement. Many countries have entered into bilateral agreements to adopt a higher degree of protection in addition to the baseline intellectual property requirements established under the TRIPS agreement. These TRIPS+ or TRIPS-Plus standards can be expressed in a variety of ways. These agreements' broad goals are as follows:

- The enactment of legislation to prevent circumvention of Digital Rights Management systems This was made possible by the WIPO Performances and Phonograms Treaty of 1996 and the World Intellectual Property Organization Copyright Treaty;
- Tougher limitations on patent compulsory licenses;
- More forceful enforcement of patents. The recommendations for WIPO and European Union rules on intellectual property enforcement have been seen more generally in this endeavor. The 1996 WIPO Copyright Treaty was put into effect by the 2001 EU Copyright Directive;
- The effort to get a WIPO Broadcasting Treaty created, which would grant broad-

casters (and possibly webcasters) exclusive rights over the copies of works they have distributed.

5. The separate Doha Declaration

At the WTO's Fourth Ministerial Conference in Doha, Qatar, on November 14, 2001, the Declaration on the TRIPS Agreement and Public Health was unanimously accepted by WTO member governments.² Its goal is to allay worries that the TRIPS Agreement would make some medications difficult for patients to get in underdeveloped nations. In order to encourage innovation, patent rights are granted to inventors. That involves developing new medications. The TRIPS Agreement, which has been in effect since 1995, also makes it legal for governments to impose a variety of restrictions on intellectual property rights, including those related to public health. Some members and public interest organizations questioned whether the TRIPS Agreement's flexibility was enough to assist public health, particularly in promoting both inexpensive access to already available medications and research and development into new ones. It was questioned whether the WTO and its members would interpret this flexibility in a wide, pro-public-health manner. Governments were worried about whether they would feel free to utilize this flexibility fully without worrying about pressure from industry or trading partners.

In several ways, the special statement addresses these worries. First, it underscores that governments of WTO members are free to take actions to protect the public's health without being hindered by the TRIPS Agreement. It confirms that the members have the freedom to make full use of the TRIPS Agreement's flexible provisions. Second, *the declaration clearly states that the TRIPS Agreement must be interpreted and put into effect in a way that supports the right of WTO members to safeguard the public health and, in particular, to advance universal access to medicines.*

It also emphasizes how crucial the TRIPS Agreement's goals and guiding ideals are when interpreting its clauses. Although the TRIPS Agreement's Articles 7 ("Objectives") and 8 ("Principles") are not directly mentioned in the declaration, developing country members place a high value on these clauses. Therefore, these declarations offer crucial assistance to both individual members and, in the case of conflicts, to WTO dispute settlement authorities. Third, the proclamation offers some crucial explanations of a few of the TRIPS Agreement's flexibilities. While doing so, it upholds members' obligations under the TRIPS Agreement. Regarding mandatory licensing, the declaration makes it clear that each member is allowed to choose the criteria for granting licenses. This, for instance, is a helpful refutation of the opinion that is occasionally voiced that the existence of an emergency is a prerequisite for mandatory licensure.

In relation to compulsory licensing, the TRIPS Agreement makes reference to national emergencies and other situations requiring immediate action. However, this is just meant to point out that, in these situations, it is not necessary to first attempt

² WTO Agreement: The separate Doha Declaration explained.

to secure a voluntary license before turning to compulsory licensing. The declaration makes it clear that each member has the authority to decide what counts as a national emergency or another situation requiring immediate attention, and that public health crises, such as the HIV/AIDS, tuberculosis, malaria, and other epidemics, may fall under this definition.

6. Patents and compulsory licensing of HIV/AIDS drugs: the experience of Kenya

The primary scapegoats for the issue of AIDS medicine availability in Kenya have been identified as patents, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and Kenya's Industrial Property Act, 2001. Due to this, efforts to develop a more practical national health policy and strategy to address the issue have been hindered. Surprisingly, inadequate care and assistance are also linked to AIDS-related deaths. In general, AIDS threatens Kenya's ability to survive, develop, produce, and compete. Dr. Patrick A. Orege (2004), the Director of the National AIDS Control Council (NACC), reports that there are 1.5 million people living with HIV/AIDS (PLWHA) in Kenya, where the daily toll from AIDS has reached nearly 300.

There have recently been claims that even the lower estimate of the prevalence of HIV in Africa is excessive and that the actual prevalence could be as much as 25% lower. Revisions to the assumptions made about the representativeness of the data sources used to generate national prevalence rates are the main reason of downward revisions in estimated prevalence rates. For instance, HIV rates are often greater in small towns than they are in villages, yet data from prenatal clinics in small towns are frequently used to estimate rates in rural regions, which causes overestimation. Prevalence estimates are typically lowered when population-based techniques for determining HIV prevalence become more prevalent.

Due to the royalties that must be paid to patent holders under the TRIPS Agreement and Kenya's Industrial Property Act, 2001(7), as well as the lack of adequate research and development (R and D) on diseases affecting Kenyans, AIDS medications are expensive. Non-governmental organizations (NGOs) have argued that more than 50% of Kenyans live on less than \$1 per day and cannot afford the pricey antiretroviral (ARV) drugs or to maintain the optimal nutrition levels associated with effective drug use. These NGOs include Médecins Sans Frontières (MSF), Action Aid, and other health campaigners (Supakankunti, 1999).

Additionally, there have been disputes over mandatory licensing. First, a lot of interested parties contend that Kenyan businesses lack the ability to produce or distribute such pharmaceuticals. The pharmaceutical business in Kenya is predominantly oligopolistic, according to NGO activists and others, and companies have not been eager to process medications under a mandatory license. Third, the availability of AIDS medications has exposed more fundamental issues with health policy: even non-patented medications have been difficult to obtain, or they have gone bad in central storage facilities, or they have been stolen by resentful Ministry of Health

bureaucrats. In order to ensure that the TRIPS Agreement does not conflict with the public interest, including public health, Kenya has argued that the TRIPS Agreement should take into account the socioeconomic development of Kenya and other developing nations. The TRIPS Council should also work closely with all stakeholders to this end. Access to medications to treat public health issues and nutrition are among Kenya's top priorities. The country has taken the view that while patent protection is encouraged, the legislation should be relaxed to aid in research and development. The relaxation must be used in a way that respects the patent holder's rights. These concerns have been advanced in large part because to the major negotiators. Within the WTO, Kenya, South Africa, Malawi, and Lesotho launched a push to loosen medication patent protection. The reason why this campaign was effective, according to activists and other participants, was because they partnered closely with other governments. In addition to lobbying decision-makers in the European Union (EU) and the United States, where significant pharmaceutical corporations were headquartered, NGOs claim credit for aiding poor countries in drafting legislation for the projects.

The African Group, of which Kenya has been a leader, noted a number of issues with the TRIPS Agreement.

Firstly, Article 31(f) of the TRIPS Agreement limits the use of forced licensing to granting permission "primarily for the supply of the domestic market of the member authorizing such use." This implies that a nation using a mandatory license must produce the goods domestically for the domestic market. Therefore, the nation has to have enough capacity for indigenous production. Most underdeveloped nations don't experience this. There are three primary issues: I Kenya and many other developing nations contend that they lack sufficient local industrial capacity and are too poor to establish factories;

Secondly, Representatives of developed and developing nations participated in the series of meetings held to carry out the Declaration's mandate. Kenya required a broader perspective in the solution's design and an interpretation of the successful use of compulsory licensing in order to support strategies to meet the members' present demands, together with the other 41 members of the African Group that it chaired. Thirdly, Kenya lobbied for the deletion or modification of Article 31(f) of the TRIPS Agreement, as well as for later interpretations to ensure Kenya had enough industrial capability to employ compulsory licensing. To guarantee openness and avoid divergence, the EU supported the proposal under certain conditions. As the end of 2002 deadline outlined in the Declaration approached, no decision had been made. On November 24, 2002, the initial decision was taken, however the African Group complained that it was inadequate and impractical. It viewed this as "a step back from Doha" since it added new constraints to the TRIPS Agreement's existing flexibility.³

³ Nelson Ndirangu, Kenya's trade attaché in Geneva, on behalf of the African Group.

7. Conclusion

In conclusion, it must be argued that the old approach of linking foreign aid to politics must not be used to handle the fight against HIV/AIDS. Kenya has to approach the fight against HIV/AIDS with the same passion and commitment that the rest of the world uses to combat terrorism. Kenya needs leadership and regional and global cooperation to achieve this. It is not very useful to move the goalposts and point the finger at unimportant issues like patents, the Industrial Property Act of 2001, TRIPS, and the WTO. Effective public health policy, legal, structural, and administrative reforms are crucial, as are revisions to the law governing research and development and patents.

References

- Bermudez, J. Epsztejn, R. Oliveira, M. A. and Hasenclever, L. (2000). The WTO TRIPS Agreement and Patent Protection in Brazil: Recent Changes and Implications for Local Production and Access to Medicines.
- Braga, C. P. Fink, C. (2001). Trade-related Intellectual Property Rights: From Marrakech to Seattle, in The world trade organization millennium round.
- Kiri, L. (2023). Global Migration strategies: Albanian migration after 1990. *Balkan Journal of Interdisciplinary Research*, Vol. 9. No. 2.
DOI: <https://doi.org/10.2478/bjir-2023-0010>
- Orege, P. (2004). The Need for Antiretrovirals. Sunday Standard (Nairobi).
- Scherer, F. M. (2001). The Innovation Lottery, in Dreyfuss, Zimmerman and First eds. Expanding the boundaries of intellectual property. innovation policy for the knowledge society.
- Sihanya, B (2005). Constructing Copyright and Creativity in Kenya: Cultural Politics and the Political Economy of Transnational Intellectual Property., JSD (doctoral) dissertation, Stanford Law School.
- Supakankunti, S. (1999). Study of the implications of the WTO TRIPS agreement for the pharmaceutical industry in Thailand.
- Stasa, I. Dedej, A. (2023). Transitional Justice as a tool for polarization in Albania. *European Journal of Economics, Law and Social Sciences*, Vol. 7. No. 3.
DOI: <https://doi.org/10.2478/ejels-2023-0012>
- TRIPS Agreement (as amended on 23 January 2017)".
- WTO Agreement: The separate Doha Declaration explained.