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# FROM PATENT TO PATIENT: LEVERAGING TRIPS FLEXIBILITIES TO OVERCOME IP BARRIERS TO MEDICINES

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**Annotation:**
This article explores the intersection of intellectual property (IP) rights and the right to public health within the framework of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It examines how TRIPS flexibilities, such as compulsory licensing, parallel imports, and exceptions to patent rights, can be effectively used by developing countries to ensure access to essential medicines while complying with international IP obligations. Special attention is given to the 2001 Doha Declaration, which reaffirmed the rights of WTO members to prioritize public health.

**Keywords:** TRIPS Agreement, intellectual property rights, public health, TRIPS flexibilities, compulsory licensing, access to medicines, pharmaceutical patents, generic drugs, Doha Declaration, WTO.

The possibility that trade agreements and globalization may have a detrimental effect on access to medications was first brought up by the World Health Assembly in 1996. The adopted resolution, "Revised Strategy on Medicines," assigned WHO the responsibility of examining how WTO operations affect national health systems and suggesting collaborative approaches to address the issues found.[1]
WHO's major initiatives in the area of medicines are outlined in the WHO Medicines Strategy, which was approved by the 54th World Health Assembly (WHO resolution

[1] Board, E. (2024). WHO medicines strategy: revised procedure for updating WHO's Model List of Essential Drugs: report by the Secretariat. *Who.int.* [online] doi:https://doi.org/EB109/8.

54.11).[2] The initiative seeks to save lives and enhance public health by bridging the significant disparity between the potential of critical medications and the actual circumstances where these medicines are inaccessible, dangerous, substandard, and misapplied for millions of people.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), established under the Final Act of the Uruguay Round in 1994, offers comprehensive universal legal protection for the rights of pharmaceutical producers inside the WTO framework.

According to TRIPS' goals and principles outlined in Articles 7 and 8, intellectual property rights need to "contribute to the promotion of economic and social welfare." The TRIPS Agreement and Public Health Declaration (also known as the "Doha TRIPS Declaration") was agreed during the Fourth WTO Ministerial Conference in Doha, Qatar, in 2001. [3]

Naturally, the primary advantage of the TRIPS Agreement accumulates to the knowledge-intensive pharmaceutical sector, which is distinguished by substantial investment in research and development during the initial phases of product creation and the susceptibility of the final product to imitation. Articles 27-34 of the TRIPS Agreement are applicable to patents and are directly relevant to public health and human development issues.

The cost of pharmaceuticals is a crucial determinant of healthcare accessibility. The cost of patented pharmaceuticals significantly exceeds that of generics, and several developing nations possess the technological capability to manufacture medications in generic form. Other nations possess the capability to choose the formulation of a medicine, but lack the ability to manufacture the active components. Some nations are entirely reliant on medicine imports. The ramifications of TRIPS for nations dependent only on imported patented pharmaceuticals remain unclear.

Patent protection has significantly enhanced the pharmaceutical business in industrialized nations by providing essential incentives for continued innovation.

[2] www.who.int. (n.d.). *WHO/HAI project on medicine prices and availability*. [online] Available at: https://www.who.int/teams/health-product-and-policy-standards/medicines-selection-ip-and-affordability/who-hai-project-medicine-prices-and-availability.

[3] World Trade Organisation (2017). WTO | Intellectual Property (TRIPS) - *TRIPS and Public Health*. [online] Wto.org. Available at: https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm.

Indian researchers produced a report titled "Patterns of Drug Use in Third World Countries," highlighting that several factors affect drug accessibility.[4]

These include inadequate public resources for health care, excessive self-medication, poor governance and coordination, a lack of basic infrastructure, inadequate staff training, poor financial resource allocation, such as between rural and urban areas, including medications and vaccines, and a lack of adequate infrastructure for health care. Resolving issues in the context under discussion is particularly challenging since all of the concerns linked to the factors listed, mainly those pertaining to drug accessibility, need to be addressed concurrently.

One of the most critical aspects of maintaining widespread access to vaccines and medications is evaluating the impact of patent protection. It is critical to strike a balance between patent protection to encourage the discovery, development, and commercialization of new medicines, so giving an incentive for more scientific findings, and patent protection to limit access to current medicines and vaccines. The TRIPS Agreement requires WTO members to preserve patents on the manufacture of a product, including medicines and vaccines, for at least 20 years after registration. This requires member nations to patent innovations in the area of health care.[5]

According to WTO experts, the TRIPS Agreement provides states with extensive flexibility in how to apply their own patent law, as long as they fulfil the fundamental requirements, including the patentability criteria outlined in the TRIPS Agreement. As a result, developing nations are free to define inventions, determine what constitutes a patent, provide rights to patent holders, and allow exceptions to patentability, provided that they fully abide by the terms of the TRIPS Agreement. According to Elizabeth Kuan, the existence or absence of intellectual property protection in underdeveloped nations only serves to encourage research on illnesses that are common there.[6]

[4] World Health Organization, "Access to Medicines – Intellectual property protection: impact on public health", WHO Drug Information, vol.19, No.3 (2005).
[5] WTO (2024b). WTO | intellectual property (TRIPS) - agreement text - standards. [online] www.wto.org. Available at: https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.
[6] WIPO Document A/39/13 add.3. The Impact of the International Patent System on Developing Countries: A Study by Elizabeth Ng Siew Kuan.

Therefore, drug prices are influenced by a wide range of factors, including supply and demand, the prescription system and administration techniques, production costs, market competition, taxes, exchange rates, royalties paid to the patent holder from the sale of patented medicines, the degree of price flexibility for various drugs, and the process of wholesale and retail sales.

The TRIPS Declaration acknowledges the entitlement of countries to completely exploit the flexibilities of the TRIPS Agreement to safeguard public health and advance universal access to medicines. Parallel imports and compulsory licensing are among the intellectual property system instruments that can be pivotal in facilitating market segmentation and differential pricing. [7]

It is crucial to highlight that "the implications of the TRIPS provisions concerning the exhaustion of intellectual property rights, specifically Article 6, permit each Member State to formulate its own exhaustion regime without infringing upon the national treatment stipulations of Articles 3 and 4."[8]

Disparities in drug prices among countries can result in cost reduction via parallel importation. The parallel import strategy entails acquiring pharmaceuticals in nations with affordable prices and transferring them into a country where access to these medications is restricted due to inflated costs. The TRIPS Agreement explicitly acknowledges the entitlement of nations to engage in parallel imports based on the principle of international exhaustion of intellectual property rights.[9]

Regarding parallel commerce between developed and developing countries generally, it is certain that the laws of the majority of wealthy nations provide benefits in the form of parallel import restrictions. By market segmentation, they assist preserve price differences, provide developing countries with possible benefits, and support lower pricing in those regions.[10]

When South Africa attempted to employ the patent expiration principle, which is in use in governments like Argentina, Japan, Australia, and the US, to authorise parallel

[7] World Trade Organization, "Compulsory licensing of pharmaceuticals and TRIPS." Available from https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm

[8] Paragraph 5(d) of the TRIPS Declaration on Public Health (WT/MIN(01)/DEC/W/2) at http://www.worldtradelaw.net

[9] Malichenko V.S. International legal mechanisms for ensuring safe circulation of medicines: Diss. … Cand. of Law. – M., 2015. – P. 118.

[10] Ibid.

imports of drugs, it encountered problems. Major pharmaceutical companies filed lawsuits in response to the South African experience, but these were subsequently dismissed. These incidents show that there is debate and difficulty in putting TRIPS regulations into practice.

The voluntary price reductions made by many major pharmaceutical corporations are a prominent illustration of a differentiated pricing approach.[11] Some HIV and AIDS medications now cost 90% less. Even with these price reductions, the most impoverished nations may still find it difficult to afford these medications.

Article 31 of TRIPS permits the authorisation of patent usage without the patent holder's approval. Compulsory licenses may be issued on a case-by-case basis, depending on the merits of certain corporations. Licensing should only be implemented when all reasonable attempts to obtain voluntary licensing have not yielded the anticipated outcomes, unless under extraordinary circumstances within a specific nation. Licenses will be granted for priority domestic use for a designated duration and shall be non-exclusive. TRIPS permits compulsory licensing in particular circumstances, namely for practices that undermine competitive freedom, for state use for non-commercial objectives, and for dependent patents.[12]

Compulsory licensing is a mechanism used by the TRIPS Agreement to reconcile access to critical medicines with the encouragement of research for novel pharmaceuticals.[13] However, experience illustrates the challenges that developing nations have in executing Article 31 of the TRIPS Agreement.

Consequently, compulsory licensing serves as a mechanism enabling the state or independent entities to acquire the right to use a patented medication without the consent of the patent owners. In this circumstance, the patent holder receives

[11] Gro, H., Land et al. (2002). *WTO AGREEMENTS AND PUBLIC HEALTH*. Available from https://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf.

[12] Beall, Reed and Randall Kuhn, "Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: a database analysis," PLoS Medicine, vol. 9, No. 1 (2012); Kohler, Jillian and Kristina Lybecker, "AIDS Policy and pharmaceutical patents: Brazil's strategy to safeguard public health" The World Economy, vol. 28, No. 2 (2005).

[13] WTO (2024b). WTO | intellectual property (TRIPS) - agreement text - standards. [online] www.wto.org. Available at: https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm

remuneration as stipulated by legislation. Compulsory licensing has effectively reduced medicine costs by promoting competition among generic producers.[14]

The Doha Declaration explicitly affirms that states possess the authority to grant compulsory licenses and to establish the criteria for their issuance. Nonetheless, several issues still unaddressed.[15] To guarantee sufficient access to pharmaceuticals, nations "lacking adequate manufacturing capacity" should include those unable to generate active components and formulations. This group should also include nations capable of producing generics, although without a local market that would guarantee the viability of such manufacturing.

The importation of generics by these nations under Article 31 of the TRIPS Agreement necessitates clarification of the compulsory licensing requirements by both the importing and producing countries. Article 30 of the TRIPS Agreement offers a more straightforward and easily administered approach to attain the same goals. The goal of guaranteeing access to medicines may be achieved via this document, contingent upon the TRIPS Council offering suitable explanation.

It would be advantageous for developing countries to include compulsory licensing measures into their national law, in alignment with the TRIPS Agreement, to enhance access to affordable medications via the importation of local products.

Developing nations and other countries with manufacturing and export capabilities should implement appropriate legislative measures, in accordance with the TRIPS Agreement, to facilitate compulsory licensing for export. Experts and academics have divergent views on the prudence of implementing compulsory licensing to enhance access to patented pharmaceuticals. Researchers assert that this technique fosters a "dynamic competitive environment that may curtail long-term price escalations." The Commission on Intellectual Property Rights asserts that compulsory licensing should not be seen as the exclusive or universal means of

[14] World Trade Organization, "Compulsory licensing of pharmaceuticals and TRIPS." Available from https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

[15] Reorienting Global Trade to Benefit People. Russian-language edition of the book «Making Global Trade work for people» 2003. Chapter 11. – C.12 www.trade.ecoaccord.org

protection, but rather as a significant instrument within a holistic framework designed for prevention of abuses in intellectual property.[16]

The TRIPS Declaration articulates this concern: "We acknowledge that WTO Members lacking adequate manufacturing capacity in the pharmaceutical sector may encounter challenges in effectively utilizing compulsory licensing under the TRIPS Agreement….". Developing nations were urged to advocate more vigorously for a broad interpretation of the TRIPS Agreement terms, as described in the TRIPS Declaration.[17]

The fact is that the TRIPS Agreement allows a certain portion of exports to be subject to a "compulsory license in the exporting country."[18]. In this regard, the view was expressed that such export opportunities should be extended to any other country that has issued a compulsory license or to those countries that have insufficient or no manufacturing capacity in the pharmaceutical sector.[19]

Alongside the limitations established by the TRIPS Agreement, there are supplementary clauses that prohibit the compulsory issuance of licenses for the manufacture of essential medications in countries characterised by constrained markets or little profitability. In these circumstances, the need for government subsidies or the creation of government industrial facilities is underscored. Enhanced local activities and financial incentives may be necessary to promote the pharmaceutical industry's more effective engagement in addressing the issue in question.

Issuing a compulsory license may serve as a potent negotiating tool that enhances a country's stance; nonetheless, it is not a panacea for guaranteeing access to patented medications in underdeveloped nations. In practice, compulsory licenses are barely used, and the TRIPS agreement stipulates even more restrictive requirements for

[16] World Intellectual Property Organization, WIPO Intellectual Property Handbook: Policy, Law and Use (World Intellectual Property Organization, 2004), p. 3, available at www.wipo.int/edocs/pubdocs/en/intproperty/489/wipo_pub_489.pdf.

[17] Ministerial Conference, Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, dated 20 November 2001, para. 4.

[18] Scherer & Watal, TRIPS options for access to patented medicines in developing countries. Commission on Macroeconomics and Health. 2001,Working Group 4, Paper 1. note 176.

[19]Statement made on behalf of the Consumer Technology Project ("CPTesh") to the South African Competition Authority.

their acceptance. Conversely, several professionals and scholars see charity as a viable solution to this issue, relevant in circumstances when other options are unfeasible. So, it may be advantageous for particular nations (or patent holders) to contemplate the option of issuing a "voluntary or consent" license under suitable conditions, in accordance with sound business and social responsibility.[20]

Notably, the WHO, WIPO, and WTO actively collaborate to tackle the intersecting issues of public health, commerce, and intellectual property. This trilateral cooperation seeks to assist members in promoting innovation and guaranteeing fair access to vital medical technology. To guarantee consistency in policy, the three secretariats have enhanced their trilateral cooperation to promote a deeper understanding of the interconnections among public health, trade, and intellectual property policies, therefore facilitating a harmonious implementation of these policies.[21]

**In conclusion,** this chapter has examined the primary international legal instruments that the WTO framework employs to safeguard and promote public health. The examination of GATT and GATS has demonstrated that trade liberalization remains a primary objective. However, WTO law also acknowledges that member states have the authority to implement health-related measures through meticulously crafted general exceptions. The SPS and TBT Agreements demonstrate the additional influence of international standards on the development of technical regulations and food safety, which are designed to balance the protection of public health and the facilitation of trade. The TRIPS Agreement, the Doha Declaration, and Article 31bis demonstrate that individuals are still striving to achieve a balance between patent protection and equitable access to critical medications. In general, the World Trade Organization law endeavors to achieve the delicate balance between trade obligations and the most critical obligation of safeguarding human health, underscoring the significance of scientific justification, non-discrimination, and proportionality in national regulatory practices.

[20] "Corporate and Social Responsibility: Creating a Sense of Good Business, January 2000"// http://www.wbcsd.ch/templates/Template WBCSD1

[21] www.wto.org. (n.d.). WTO | intellectual property (TRIPS) - *Trilateral cooperation on intellectual property and public health.* [online] Available at: https://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm.

## REFERENCES

1. www.who.int. (n.d.). WHO/HAI project on medicine prices and availability. [online] Available at: https://www.who.int/teams/health-product-and-policy-standards/medicines-selection-ip-and-affordability/who-hai-project-medicine-prices-and-availability.
2. World Trade Organisation (2017). WTO | Intellectual Property (TRIPS) - TRIPS and Public Health. [online] Wto.org. Available at: https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm.
3. World Health Organization, "Access to Medicines – Intellectual property protection: impact on public health", WHO Drug Information, vol.19, No.3 (2005).
4. WTO (2024b). WTO | intellectual property (TRIPS) - agreement text - standards. [online] www.wto.org. Available at: https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.
5. WIPO Document A/39/13 add.3. The Impact of the International Patent System on Developing Countries: A Study by Elizabeth Ng Siew Kuan.
6. World Trade Organization, "Compulsory licensing of pharmaceuticals and TRIPS." Available from https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm
7. Gro, H., Land et al. (2002). WTO AGREEMENTS AND PUBLIC HEALTH. Available from https://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf.
8. Beall, Reed and Randall Kuhn, "Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: a database analysis," PLoS Medicine, vol. 9, No. 1 (2012); Kohler, Jillian and Kristina Lybecker, "AIDS Policy and pharmaceutical patents: Brazil's strategy to safeguard public health" The World Economy, vol. 28, No. 2 (2005).
9. Scherer & Watal, TRIPS options for access to patented medicines in developing countries. Commission on Macroeconomics and Health. 2001,Working Group 4, Paper 1. note 176.
10. www.wto.org. (n.d.). WTO | intellectual property (TRIPS) - Trilateral cooperation on intellectual property.