



INTERNATIONAL LAW
JOURNAL

**WHITE BLACK
LEGAL LAW
JOURNAL**
**ISSN: 2581-
8503**

Peer - Reviewed & Refereed Journal

The Law Journal strives to provide a platform for discussion of International as well as National Developments in the Field of Law.

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EVALUATING TRIPS FLEXIBILITIES AND PUBLIC WELFARE STRATEGIES IN INDIA AND DEVELOPING JURISDICTIONS.

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Abstract

The Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPS**) establishes binding minimum standards for intellectual property protection all over the World Trade Organization (WTO) member states. While intended to harmonize patent protection and stimulate innovations, its uniform framework has generated significant developmental concerns, particularly in countries with limited technological capacity. In this research paper we examine TRIPS flexibilities as instruments of regulatory balance and also evaluate their effectiveness in advancing public welfare within India and selected Global South jurisdictions. Through a comparative doctrinal analysis of the topic, this study argued that TRIPS embodies a negotiated equilibration between private patent rights and sovereign authority for protecting public interest. **Articles 7 and 8** of the **TRIPS** Agreement emphasize technological dissemination, social inequality and public welfare, and the prevention of abuse of rights. Further the Doha Declaration on Public Health reaffirms the primacy of access to medicines. India represents a valued paragon of strategic utilization of TRIPS flexibilities, specially through its patent law framework and landmark compulsory licensing practices. On the contrary many developing countries in Africa region and Latin America have faced institutional, political, and economic curtailments in implementing to similar safeguards. This study also compares India's legislative alacrity with experiences from countries such as Brazil and South Africa to highlight variations in enforcement, political will, and external trade pressures. The analysis reveals that while TRIPS flexibilities formally exist, their practical effectiveness depends on domestic legal capacity, resistance to TRIPS-Plus obligations, and regional cooperation among developing nations. Global health emergencies have further exposed structural inequities in access to pharmaceuticals and essential technologies,

underscoring the continuing relevance of a development-oriented interpretation of TRIPS.

This paper reckon that TRIPS flexibilities are not exceptional divergence from patent protection but essentially structural correctives embedded within the International Intellectual Property Law. Strengthening their operationalization is conclusive for reducing Global inequality within nations in alignment with Sustainable Development Goal.

Keywords: TRIPS Flexibilities; Public welfare; Compulsory Licensing; Global Inequality; Intellectual Property

1.Introduction

The global interconnectedness of intellectual property prototype through the TRIPS Agreement marked a transformative moment in international economic governance. By assimilating intellectual property protection into the collaborative trade system, TRIPS exalted patent rights to enforceable international global obligations. Nevertheless, this harmonization transpired amidst stark evolutionary asymmetries between industrialized and developing economies. we will examines in this paper TRIPS flexibilities as instruments of regulatory balance and also evaluates their effectiveness in advancing public welfare within India and selected Global South jurisdictions. Through a comparative doctrinal analysis of the topic, this study argued that TRIPS embodies a negotiated equilibration between private patent rights and sovereign authority for protecting public interest.

For cutting-edge nations, stronger patent framework incentivize research and innovation. For evolving countries, specifically those in the Global South, rigid protection may augment dependence on imported technologies and restrict access to essential medicines. This conflict heightens a fundamental question: may TRIPS accommodated developmental equity within its legal structure? In this research paper we will explores these types of questions through a comparative analysis of India and mentioned Global South jurisdictions. The analysis reveals that while TRIPS flexibilities formally exist, their practical effectiveness depends on domestic legal capacity, resistance to TRIPS-Plus obligations, and regional cooperation among developing nations. Global health emergencies have further exposed structural inequities in access to pharmaceuticals and essential technologies, underscoring the continuing relevance of a development-oriented interpretation of TRIPS.

2. Legal and conceptual Framework of the TRIPS

TRIPS does not only works as a purely protectionist instrument but also states that, as per Article 7 of the TRIPS elaborate that intellectual property protection should contribute to technological innovation and global public welfare. Also Article 8 permitted to member states of the TRIPS to adopt suitable measures important for protecting public health and prevent abuse of intellectual property rights.

The TRIPS Agreement adopted in 1994 as part of the WTO framework, established minimum international standards for the protection and enforcement of intellectual property rights, including pharmaceutical patents.¹ Before TRIPS, many developing countries did not grant patent protection for medicines at all; after its adoption, all WTO members were required to provide 20-year patent protection for pharmaceutical products and processes.² This fundamentally reshaped the legal landscape for access to medicines, effectively limiting the production and import of affordable generic drugs in many countries.³

Recognizing that rigid IP rules could harm public health, especially in resource-poor settings, TRIPS included several legal safeguards-commonly referred to as “flexibilities.”⁴ The TRIPS Agreement comprises multiple public-health-oriented flexibilities which permits governments to balance patent protection with access to medicines. At the foundation is sovereign policy space, enabling countries to define strict patentability criteria, implement pre- and post-grant opposition systems, enforce robust disclosure requirements, and shape clear infringement standards to prevent unwarranted monopolies.⁵ When patents nonetheless create access barriers, corrective measures are available, including compulsory licensing, government use authorizations, competition-law interventions against abusive practices,⁴ and judicial discretion to refuse provisional injunctions where the public health is on the line. The TRIPS flexibilities also include other pro-competitive mechanisms such as the ‘Bolar exception’, parallel importation, and a flexible interpretation of test-data protection under Article 39.3 each designed to facilitate timely generic entry and/or lower prices.⁵ Finally, the agreement includes

¹ WTO, TRIPS Agreement.

² Cecilia Oh, “TRIPS and pharmaceuticals: A case of corporate profits over health”, Third World Network, August-September 2000. Available from <https://twon.my/title/twr120a.htm>.

³ Carlos M. Correa, Integrating Public Health Concerns into Patent Legislation in Developing Countries (Geneva. South Centre, 2000). Available from <https://www.southcentre.int/wp-content/uploads/2017/06/Bk-2000-Integrating-Public-Health-Concerns-into-Patent-Legislation-EN.pdf>. ⁴ Carlos M. Correa, "Interpreting the Flexibilities Under the TRIPS Agreement", in Carlos M. Correa and Reto M. Hilty, eds., Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law (Springer, 2022). Available from <https://doi.org/10.1007/978-3-030-83114-1>. ⁵ WTO, TRIPS Agreement, Art. 27-30.

⁴ Ibid, Art. 31.

⁵ Ibid., arts. 6, 30, 39.3. Also see Correa, "Interpreting the Flexibilities Under the TRIPS Agreement."

defensive safeguards: a pharmaceutical patent exemption for Least Developed Countries extended until at least 2033.⁶ Additionally, the TRIPS Agreement does not necessitate WTO members to accept broader protections than that stipulated in the Agreement. Together, these flexibilities form an integrated framework that countries can use to promote access to affordable medicines while remaining fully compliant with TRIPS.⁷⁸

The Doha Declaration on TRIPS and Public Health (2001) reaffirmed that TRIPS should not prevent States from taking measures to protect health.¹⁰ It clarified that TRIPS “should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”¹¹ The Declaration precisely confirmed the right of WTO members for granting compulsory licenses, and also determines what a national emergency, and select their own methods for implementing TRIPS obligations. It also gives a basis for expanding transition periods for LDCs and introduced mechanisms to help countries without manufacturing capacity import generic medicines under a compulsory license.

Despite these legal and policy possibilities, the use of TRIPS flexibilities has been politically sensitive and procedurally complex.⁹ Legally, the Doha Declaration elucidated ambiguities in TRIPS and strengthened the legitimacy of using flexibilities, thus implementation has depended on national capacity and political will spheres where external pressures and institutional constraints remains considerable. The foundation for treating access to medicines as a human rights issue lies in the right to health, enshrined in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).¹⁰ The Covenant, which came into force in 1976 and has been ratified by over 170 countries, recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” This contains not just access to health services but also to the access to essential medicines specifically those needed to treat life-threatening or chronic conditions of human health.

The United Nations (UN) Committee on Economic, Social and Cultural Rights, which observed the implementation of the ICESCR, has interpreted this right expansively. In its General

⁶ World Trade Organization, document WT/L/971. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/L/971.pdf>.

⁷ South Centre, “A Public Health Related Approach to Intellectual Property Rights: Public Health Related Flexibilities in the TRIPS Agreement”. Available from <https://ipaccessmeds.southcentre.int/wpcontent/uploads/2018/12/Public-Health-Related-Flexibilities-in-the-TRIPS-Agreement.pdf>.

⁸ World Trade Organization, document WT/MIN(01)/DEC/2, Available from <https://www.wto.org/english/thewtoe/minist e/min01 e/ trips e.htm> ¹¹ Ibid, Para 4.

⁹ UNHLP, “Final Report”.

¹⁰ International Covenant on Economic, Social and Cultural Rights (1966), art. 12.

Comment No. 14 (2000), the Committee made clear that States have a “core obligation” to provide essential drugs, as defined by the World Health Organization (WHO), and that this obligation is non-derogable-meaning it cannot be delayed due to lack of resources or capacity.

¹¹The General Comment also emphasized four dimensions of access: availability, accessibility, acceptability, and quality-standards that are widely referenced in health policy and international law.¹²

Built-in on this legal base, the UNHRC plays a key role in interpreting and reinforcing the right to health throughout resolutions, special procedures, and expert reports. Although its resolutions are not legally binding, they carry significant normative weight. They reflect collective expectations about how international law should be applied and serve as soft law instruments that shape global discourse and guide State behaviour.¹³¹⁴

During the past 2 decades, the UNHRC has adopted multiple resolutions, examined below, linking access to medicines with the right to health, explicitly referencing States’ obligations under the ICESCR and encouraging the use of TRIPS flexibilities.¹⁷ These resolutions often underscore the responsibility of both governments and international institutions to avoid IP policies that undermine access, especially in low-income settings. They have also supported the mandate of the Special Rapporteur on the Right to Health, whose thematic reports¹⁵ have provided detailed legal guidance on reconciling IP rights with human rights.

These provisions shows the embedded principle of balance. The agreement therefore includes normative capacity for states to align patent protection with developmental objectives.

Intellectual property rights are conventionally specifies as incentives for innovation and technological progress. However, contemporary scholarship increasingly examines intellectual property through the lens of distributive justice, particularly in the context of developing countries. Strong patent protection may stimulate research and development, but it can also created hurdles to access where essential technologies or medicines become unaffordable. In such circumstances, the international intellectual property framework must balance private proprietary interests with broader social objectives. The TRIPS Agreement reveals this harmony through Articles 7 and 8, which emphasize that intellectual property protection should contribute to social and economic welfare. From this point of view, TRIPS flexibilities operate

¹¹ United Nations Committee on Economic Social and Cultural Rights, document E/C. 12/2000/4, para,43.

¹² Ibid, paras, 43-44.

¹³ UNHRC, A/HRC/RES/12/24

¹⁴ United Nations Human Rights Council, document A/HRC/23/14. Available from <http://daccessods.un.org/access.nsf/Get?Open&DS=A/HRC/RES/23/14&Lang=E>

¹⁵ See, e.g., United Nations General Assembly, document A/HRC/11/12. Available from <https://digitallibrary.un.org/record/652915?v=pdf#files>.

as mechanisms that enable states to protect public health while maintaining compliance with international trade obligations.

In practical situation, these resolutions establish political and moral pressure on States and international bodies. Whereas they do not obliged adherence in the way treaty obligations do, they contribute to norm-building, influence domestic and international health policy agendas, and are often cited by advocacy groups, courts, and legislators as authoritative interpretations of international law.

Eventually, the UNHRC's contributions aids reframe access to medicines not as an optional policy choice but as an obligation embedded in the ICESCR. Notwithstanding their effectiveness depends on whether States adopt the measures they encourage-including the use of TRIPS flexibilities.

A commitment to equity lies at the heart of the right to health. This requires States to ensure that access to essential medicines is not determined by socio-economic status, geographic location, or other structural factors that systematically disadvantage certain populations.

General Comment No. 14 makes this clear: the right to health encompasses not only availability and affordability, but also non-discrimination and the prioritization of vulnerable and marginalized groups. Seen through this lens, TRIPS flexibilities are not peripheral legal tools but central mechanisms for fulfilling core human rights obligations. By enabling competition, they allow States to narrow price gaps that disproportionately burden low-income households and to extend treatment to populations historically excluded from timely or affordable care. Thus, the use of TRIPS flexibilities is not a discretionary policy option-it is an essential means of advancing the equitable realization of the right to health.

3. TRIPS Flexibilities

The terminology used to refer to the policy space available for the implementation of the TRIPS Agreement has evolved. Expressions such as "room to maneuver," "margins of freedom," "safeguards," and "margin of discretion" were used in the early studies and reports that identified various aspects of such space. Currently, the diversity of legislative options available under said Agreement is generally known as 'TRIPS flexibilities.'

The term "flexibility appears in the Preamble (sixth paragraph) and in Article 66.1 of the TRIPS Agreement but it is used there with a broader meaning. It indicates that least-developed countries (LDCs) are not bound to comply with the TRIPS Agreement obligations (except Articles 3 through 5) during the transition period:

In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of...

The terminology “TRIPS flexibilities does include the exemption for LDCs, but it also encompasses possible variations in the manner in which the TRIPS Agreement’s provisions are interpreted and implemented as they are applied to countries actually subject to them. Such terminology was used for the first time with this latter meaning in the context of the WTO in paragraph 4 of the Doha Declaration.” Said paragraph states:

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

The Declaration confirmed the availability of a number of flexibilities. Its adoption was a response to the concerns of developing countries about the obstacles they faced when seeking to implement measures to promote access to affordable medicines, without limitation to certain diseases, in the interest of public health.²⁰

TRIPS incorporates several legal mechanisms designed to maintain equilibrium between intellectual property protection and public welfare considerations. These mechanisms, commonly referred to as “TRIPS flexibilities,” allow member states to adapt patent protection to domestic policy needs. Among the most significant of these safeguards are compulsory licensing, parallel importation, and transitional arrangements and so on for least developed countries.

3.1 Compulsory Licensing

Article 31¹⁶ permits governments to authorize the use of patented inventions without consent under specific conditions. This mechanism serves as a safeguard against excessive pricing and supply shortages. Compulsory licensing has emerged as one of the most significant safeguards within the TRIPS framework, enabling governments to authorize the production of patented

¹⁶ The Patents Act, No. 39 of 1970, § 84 (India).

medicines without the consent of the patent holder under specific circumstances such as public health emergencies or unaffordable drug prices.¹⁷

India operationalized this provision in its patent law framework, demonstrating the practical relevance of TRIPS flexibilities.¹⁸

Compulsory licenses for the supply of medicines to countries with a lack of or Insufficient manufacturing capacity Compulsory licenses exclusively for the export of Medicines can be granted under the amendment introduced to the TRIPS Agreement in 2017 and the waiver adopted by WTO in 2003.

3.2 Parallel Importation

The doctrine of exhaustion allows countries to import patented goods sold elsewhere at lower prices. This enhances market competition and affordability.

3.3 Transitional Arrangements

Least developed countries received extended timelines to implement pharmaceutical patents, recognizing structural economic disparities.

3.4 Exemptions) for LDCs

LDCs need not grant patents for pharmaceuticals and test data Protection at least until 2033 under the extended transition period provided for under Article 66.1 of the TRIPS Agreement.

3.5 Government use

In many cases governments may decide, consistently with the TRIPS Agreement, to use patented inventions for non-commercial purposes, such as for Ensuring the supply of essential medicines.

3.6 Test data protection – The TRIPS Agreement (Article 39.3) requires WTO members to protect test data against unfair competition, which does not create exclusive rights. The Agreement is complied with if legislation on unfair competition is implemented to protect Such data.

¹⁷ Carlos Correa, Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries, 6 S. Ctr. Res. Papers (2016).

¹⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, 1869 U.N.T.S. 299.

3.7 Pre and post patent grant opposition

Procedures before patent offices provide for the possibility for third parties to contribute to the examination process through ‘observations’ Or ‘oppositions,’ whether before or after the grant of a patent, or both.

3.8 Use of competition law to address the misuse of IPRs – Competition law may be Applied to correct market distortions created through the abuse of IPRs.

3.9 Bolar exception

‘Bolar exceptions’ are important to accelerate the entry of generic Products and promote a dynamic market for medicines.

3.10 Research or experimentation exception

This exception allows research to be Conducted by third parties on patented inventions, for instance, to improve on them or derive New inventions.

3.11 Disclosure requirement, particularly for biologics the full and precise disclosure Of an invention is crucial for the patent system to perform its informational function.

4. India and TRIPS Flexibilities

India’s Patent Act incorporates public interest safeguards such as strict patentability criteria and compulsory licensing provisions. The 2012 compulsory license granted for a life-saving cancer drug marked a significant assertion of public health priorities within the TRIPS framework.¹⁹

India has also maintained resistance against expansive TRIPS-Plus commitments in bilateral trade negotiations, preserving domestic regulatory autonomy.

5. Comparative Analysis

India’s patent law framework illustrated how TRIPS flexibilities can be incorporated into domestic legislation without violating international obligations. The Patents Act includes provisions that allow compulsory licensing when patented inventions are not available at

¹⁹ The Patents Act, No. 39 of 1970, § 84 (India).

reasonably affordable prices or when public health needs are not adequately satisfied.²⁰

The landmark *Natco v. Bayer* compulsory licensing decision marked the first time the Indian Patent Office authorized a generic manufacturer to produce a patented cancer drug at a significantly reduced price.²¹ The case demonstrated that TRIPS flexibilities can operate as effective policy tools when supported by clear legislative provisions and administrative willingness.

Brazil provides another example of strategic engagement with TRIPS safeguards. Rather than frequently issuing compulsory licenses, Brazil has used the possibility of such action as a bargaining instrument to negotiate price reductions with pharmaceutical companies supplying antiretroviral medicines for HIV treatment programs.²²

In the contrary South Africa's experience illustrates the political resistance that developing countries sometimes encounter when attempting to implement public health measures affecting patent rights. Efforts to reform medicines legislation in the late 1990s were challenged by multinational pharmaceutical companies, leading to extensive litigation and international pressure.²³ Despite of the case was eventually withdrawn, it demonstrates the broader geopolitical dynamics surrounding intellectual property governance.

Bilateral trade agreements evolvingly impose standards exceeding TRIPS obligations. These provisions may threshold compulsory licensing grounds, extend patent terms, or introduce data exclusivity requirements. Such developments risk undermining the balance envisioned within TRIPS.

6. TRIPS, Recent Global Health, and Inequality

Recent global health conflicts revealed structural inequalities in vaccine production and distribution. The debate surrounding momentary IP waivers highlighted stress between innovation incentives and equitable access. The relationship between intellectual property protection and public health has been widely debated in international policy discussions, particularly regarding the affordability of essential medicines in developing countries. International organizations have emphasized that patent protection should not undermine public health objectives.²⁴

²⁰ Ibid.

²¹ *Natco Pharma Ltd. v. Bayer Corp.*, Compulsory License Application No. 1 of 2011 (Controller of Patents, India Mar. 9, 2012).

²² Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 Am. J. Int'l L. 317 (2005).

²³ Ellen 't Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines*, 3 Chi. J. Int'l L. 27 (2002).

²⁴ World Health Organization, *Public Health, Innovation and Intellectual Property Rights* (2006).

A development-oriented interpretation of TRIPS is important to protect and obstruct intellectual property from reinforcing global disparities.

7. Conclusion

TRIPS flexibilities incorporates integral harmony mechanisms within international intellectual property law. On the other hand, India's exposure demonstrates that proactive legislative design and political will can operationalize these safeguards efficiently. Comparative analysis of Brazil and South Africa reveals both possibilities and constraints within the Global South.

For TRIPS to align with Sustainable Development Goal 10 as mentioned Global Inequalities, member states must maintained regulatory autonomy, strengthen domestic capacity, and resist excessive TRIPS-Plus commitments. A deliberated and equity-centred interpretation abides critical to ensuring that intellectual property law serves public welfare rather than undermines it.

