NAVIGATING TRIPS FLEXIBILITIES: APPLICABILITY AND GAPS IN MAINLAND TANZANIA

Edward Gamaya Hoseah* & Donatus Nicholas Nditi**

ABSTRACT

Anchored within the framework of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the article looks at how Tanzania, as a least developed country (LDC) and Member of the World Trade Organization, navigates its international intellectual property obligations while safeguarding public health, technological development, and access to essential medicines. It analyses key TRIPS flexibilities, including compulsory licensing, parallel importation, transitional periods for LDCs, and exceptions and limitations to patent rights. It assesses the extent to which these mechanisms have been incorporated into the Patents (Registration) Act. Special attention is given to the public health dimension, especially in light of the Doha Declaration on the TRIPS Agreement and Public Health, which affirms Members' rights to protect public health and promote access to medicines. It argues that while Tanzania has formally integrated several TRIPS flexibilities into its legal framework, significant gaps remain in operationalization and institutional capacity. Challenges include limited technical expertise in patent examination, regulatory fragmentation, weak coordination, limited use of compulsory licensing mechanisms, and external pressures arising from bilateral and regional trade arrangements that may narrow policy space. Furthermore, the study highlights practical obstacles such as insufficient awareness among policymakers and judicial actors, constrained local pharmaceutical production capacity, and limited engagement with technology transfer mechanisms envisaged under Article 66.2 of TRIPS. Through doctrinal analysis, the article concludes that the effectiveness of TRIPS flexibilities in Mainland Tanzania depends not merely on legislative incorporation but on strategic implementation, institutional strengthening, and coherent alignment between trade policy and public health priorities. It recommends enhanced capacity-building, clearer procedural regulations for compulsory licensing, improved inter-agency coordination, and stronger use of LDC transition periods to maximize policy space. Ultimately, Tanzania's experience illustrates both the protective potential and structural limitations of TRIPS flexibilities within the broader context of global intellectual property governance and development policy.

Keywords: TRIPS Agreement, TRIPS Flexibilities, Public Health, Patent Law and Mainland Tanzania

1. Introduction

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)[1] established minimum standards of intellectual property (IP) protection binding on all Members of the World Trade Organization (WTO).[2] The TRIPS Agreement also incorporates a set of flexibilities i.e. legal mechanisms that allow countries to tailor IP rules in ways that support public policy goals, particularly public health and access to medicines.[3] They are policy spaces and options within the TRIPS Agreement that members can use to adjust how IP rights are implemented, without breaching their obligations.[4]These flexibilities are especially important for developing and least-developed countries (LDCs) such as Tanzania because they empower states to mitigate the adverse effects of strict IP regimes, such as high medicine prices, while still complying with the TRIPS Agreement.[5]

Flexibilities, in this context, procure their legitimacy from the TRIPS Agreement itself and confirmed by the Doha Declaration,[6] which clarified and reaffirmed that TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and to use these flexibilities fully.[7]From its own language, the TRIPS Agreement has allowed WTO Members to exploit creative solutions to transpose into national law and practice those concepts that the TRIPS Agreement simply enunciates but does not define.[8] Examples of those flexibilities include concepts such as novelty and inventiveness; or of situations of extreme urgency for the purposes of compulsory licenses. It has allowed its least-developed country Members to be flexible in the domestic implementation of laws and regulations with a

* LL.B. (Hons), LL.M, Ph.D., Associate Professor of Law, University of Iringa
** LL.B. (Hons), LL.M, PGDLP, Ph.D., Lecturer of Law, University of Iringa
[1] Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
[2] Art.1(1).
[3] WTO, *TRIPS and Public Health*, Intellectual Property: Technical Cooperation — Key Documents. Available at https://www.wto.org/english/tratop_e/trips_e/ta_docssec3_e.htm> (accessed on 2 December 2025).
[4]Health Action International, *TRIPS Flexibilities Navigator*. Available at https://flexibilitiesnavigator.org/FAQ> (accessed on 2 December 2025).
[5] WTO, *TRIPS and Public Healthy*. Available at https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> (accessed on 2 December 2025).
[6]The Doha Declaration on the TRIPS Agreement and Public Health (2001).
[7] Canonica, *Doha Declaration on the TRIPS Agreement and Public Health.* Available at https://canonica.ai/page/Doha_Declaration_on_the_TRIPS_Agreement_and_Public_Health> (accessed on 2 December 2025.
[8]Art. 1.1 of the TRIPS Agreement.

view to, while taking heed of their special needs, enabling them to create a sound and viable technological base.[9]

It remains a fact that for developing countries such as Mainland Tanzania, the effective use of the TRIPS flexibilities remains a central legal and policy concern. This article therefore, examines the scope and legal basis of the TRIPS flexibilities, their applicability within Mainland Tanzania's domestic legal framework, existing legislative and institutional gaps, and practical challenges affecting implementation.

2. The Legal Framework for TRIPS Flexibilities

The legal framework of TRIPS flexibilities is embedded within the TRIPS Agreement, which incorporates mechanisms that allow Members to calibrate IP protection in accordance with public interest objectives, including public health, socio-economic development, and technological advancement. It is imperative to note that these mechanisms are not exceptions external to the Agreement; rather, they are integral components of its normative structure.[10] The legal framework of these flexibilities may be understood through four interrelated dimensions, which are interpretative principles, express substantive flexibilities, special and differential treatment provisions, and subsequent interpretative instruments and WTO jurisprudence.

2.1. Interpretative Foundations: Objectives and Principles

The objective of the TRIPS Agreement is to protect and enforce intellectual property rights in a manner that such protection and enforcement should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare.[11] This provision is foundational because it frames IP protection as instrumental rather than absolute. It confirms that the TRIPS Agreement seeks a balance between rights holders and public welfare.

As commentators have observed, Article 7 serves as an interpretative compass in

[9]Para 6 of the Preamble of the TRIPs.
[10] UNCTAD-ICTSD, *Resource Book on TRIPS and Development,* Cambridge University Press 2005, p. 112.
[11] Art. 7.

construing the scope of Members' obligations.[12] In fostering this objective, the members are left at liberty 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.[13] In the same spirit, the TRIPS Agreement allows measures to prevent abuse of IP rights or practices that unreasonably restrain trade.[14] Therefore, objectives and principles together form the constitutional backbone of the TRIPS flexibilities.[15] They confirm that regulatory intervention, when necessary for public interest purposes, is permissible within the TRIPS Agreement framework.

2.2. Substantive Flexibilities under TRIPS

Substantive flexibilities under the TRIPS Agreement refer to explicit treaty provisions that permit WTO Members to limit, regulate, or condition the exercise of intellectual property (IP) rights in pursuit of public interest objectives. These flexibilities are embedded within the operative provisions of the TRIPS Agreement itself and reflect a negotiated balance between private rights and sovereign regulatory authority. They operate primarily within the patent regime but extend to other areas of intellectual property law. The most significant substantive flexibilities are outlined below.

2.2.1. Compulsory Licensing

The TRIPS Agreement permits Members to authorize use of a patented invention without the authorization of the right holder, subject to specified conditions. These conditions include prior efforts to obtain voluntary authorization, except in cases of national emergency or extreme urgency; adequate remuneration; and judicial or administrative review. It was originally required that production under compulsory license to be predominantly for the supply of the domestic market.[16]

This limitation was problematic because this rule created a serious difficulty for least Developed Countries (LDCs), small developing countries, and countries with no pharmaceutical manufacturing capacity. Indeed, the core problem revolved around the

[12] Correa, C.M., *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement,* Oxford University Press, 2007, p. 87.
[13] Art. 8(1).
[14] Art. 8(2).
[15] Arts. 7 and 8.
[16] Art. 31(f).

fact that if a country cannot manufacture medicines domestically, it cannot issue a compulsory license to produce medicines itself. As a result, the same will be burdened to import large quantities from another country that issued a compulsory license because that other country must supply "predominantly" its own domestic market.[17] So the system worked only for countries that already had manufacturing capacity, which thing created urgency during the HIV/AIDS crisis in the late 1990s and early 2000s.

To fix this problem, WTO Members adopted what became known as the Paragraph 6 System, which acknowledged that countries with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing. This followed Paragraph 6 of the 2001 Doha Declaration on TRIPS and Public Health,[18] which later amended the TRIPS Agreement through Article 31bis, which entered into force in 2017.[19] Now, it is permissible to export pharmaceutical products produced under compulsory licenses to countries lacking manufacturing capacity.[20] This amendment corrected structural constraints in Article 31(f) of the TRIPS Agreement and strengthened public health safeguards.

This reform was crucial for access to HIV/AIDS treatment and public health emergencies to the Least Developed Countries like Tanzania and countries without pharmaceutical industries. It transformed compulsory licensing from a tool usable mainly by large countries (like India or Brazil) into one theoretically accessible to smaller and poorer states. However, in practice, the Paragraph 6 / Article 31bis system has been used only rarely, because it is procedurally complex, requires notifications to the WTO, involves labeling and anti-diversion measures, and can be politically sensitive. Ultimately, it can be quite fair at this juncture to assert that compulsory licensing represents one of the most significant legal flexibilities available to WTO Members.

2.2.2. Exhaustion of Rights and Parallel Importation (Article 6)

Exhaustion of rights refers to the principle that once a protected product, e.g., a patented

[17] It means mostly or mainly. So, if a country issued a compulsory license, the medicines, say, produced under that license had to be supplied mainly within that country, not exported in large quantities.
[18] WT/MIN(01)/DEC/2 (14 November 2001).
[19] WTO, *Amendment of the TRIPS Agreement*, WT/L/641 (8 December 2005), p. 1.
[20] Art. 31bis.

medicine, is lawfully placed on the market by or with the consent of the right holder, the intellectual property owner's control over the subsequent resale or distribution of that specific product is "exhausted."[21] Under Article 6 of the TRIPS Agreement, issues relating to the exhaustion of intellectual property rights are explicitly excluded from WTO dispute settlement, subject to the national treatment and most-favoured-nation provisions.[22] This means that WTO Members are free to determine their own exhaustion regime without violating the TRIPS Agreement.

Members may either adopt national exhaustion meaning IP rights are exhausted only when the product is first sold within the country; importation of the same product from abroad may be restricted or regional exhaustion meaning rights are exhausted within a regional economic area such as a customs union or international exhaustion meaning rights are exhausted once the product is placed on the market anywhere in the world, allowing importation of lower-priced goods from other countries.[23]

Parallel importation refers to the importation of genuine, lawfully marketed products without the authorization of the local IP holder. This practice is lawful if a country adopts an international or relevant regional, exhaustion regime.[24] In the context of public health, parallel importation allows countries to source medicines at lower prices from foreign markets, thereby enhancing access and price competition.

In the context, Patent rights, like other intellectual property rights, are territorial in nature.[25] This means that each patent provides its owner the exclusive right of exploiting the invention within the limits of the country or countries where the patent was granted. The Paris Convention, in its article 4bis, spells out this principle in the following words:

> (1) Patents applied for in various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or

[21] Art. 6.
[22] Ibid.
[23] UNCTAD-ICTSD, *Resource Book on TRIPS and Development,* Cambridge University Press 2005, pp. 95–97.
[24] Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*,Oxford University Press 2007, pp. 79–80.
[25] Harms, L., ibid., p. 250

not.

(2) The foregoing provision is to be understood in an unrestricted sense, in particular, in the sense that patents applied for during the period of priority are independent, both as regards the grounds for nullity and forfeiture, and as regards their normal duration.

Thus, one single invention could be the object of patent protection in several countries, creating rights that are independent from each other. The TRIPS Agreement enumerates those rights (conferred rights),[26]which includes among them the "right of importation" because the exclusive right derived from a patent could be affected by the importation of the patented product from another country. The TRIPS Agreement spells the conferred rights in the following words:

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

It is important to note that article 28 of the TRIPS Agreement contains a footnote regarding the right to prevent importation, stating that this right, "like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6 of the TRIPS Agreement.[27] However, the said article 6 does not establish which level of exhaustion, that is, whether national, regional or international, members should adopt, subject to its

[26] Art. 28.

[27] Art. 6 of the Agreement allows each WTO Member to determine its own regime on exhaustion (whether national, regional or international), subject to the national treatment and Most Favored Nation (MFN) provisions of Arts. 3 and 4 respectively.

provisions on national treatment and most-favored-nation treatment.[28]

The decision about the level of exhaustion that is appropriate for a given country is a matter of policy consideration, in which some elements are not patent related, but based on certain market situations, as Cornish[29] has stated:

> In every intellectual property law it is necessary to decide which steps in the chain of production and distribution of goods require the license of the right owner: manufacture, first sale by the manufacturer, subsequent sales and other dealings, export and import, use. In the past, legislators have often left the answer to the courts. In many cases, both in British and foreign laws, the rights are 'exhausted' after first sale by the right owner or with his consent. But often this is confined to the first sale to the territory covered by the right-it amounts to a domestic, rather than international, exhaustion. Accordingly, national rights that are subject to such limitation can still be used to prevent the importation of goods sold abroad by the national right-owner or goods which come from an associated enterprise.

The implication here entails that the possibility of enforcing the exclusive rights of patents against the importation of legitimate products varies according to the level of exhaustion of rights adopted by the country where the importation takes place. This means that parallel importation of goods into a country will not be permitted where that country's legislation provides for national exhaustion. Tanzania is good example where Patents Act provides that the rights under the patent shall not extend to acts in respect of articles which have been put on the market in the United Republic by the owner of the patent or with his express consent.[30] This provision therefore makes parallel importation in Tanzania impractical.

Such importation will be permitted into a country with a regional system of exhaustion in so far as the goods were released in a country of the region by the owner of the patent

[28] The Doha Declaration has reaffirmed that each member is free to establish its own regime without challenge.
[29] Cornish, W. R., ibid.
[30] See s. 38(2). Also, it appears that this level of exhaustion has been adopted in several SADC and the EAC countries such as Madagascar (S. 30(2).

or with his consent. In a country applying a system of international exhaustion, patented products put on the market by the owner of the patent or with his consent in any country may be imported into that country without constituting an infringement of the patent.[31] The legal significance of article 6 constitutes a major substantive flexibility because it leaves the choice of exhaustion regime entirely to Members, reinforcing regulatory sovereignty in balancing IP protection and consumer welfare.

2.2.3. Other Key Flexibilities

2.2.3.1. Bolar (Regulatory) Review Exception

The Bolar exception, also known as the regulatory review exception or limited exceptions, permits the use of a patented invention, without the patent holder's consent, for purposes of obtaining regulatory approval before the patent expires. Its objective is to allow generic manufacturers to enter the market immediately upon patent expiry, thereby avoiding de facto extension of patent monopolies. The legal basis is found in Article 30 of the TRIPS, which allows Members to provide limited exceptions to patent rights provided they satisfy the three-step test.[32] The WTO Panel in *Canada – Patent Protection of Pharmaceutical Products* upheld Canada's regulatory review exception as consistent with Article 30, confirming that such exceptions may be permissible when properly circumscribed.[33]

The position of this exception in Mainland Tanzania is governed by the Patents (Registration) Act.[34] It provides for limitations to patent rights, including acts done for experimental or scientific purposes.[35] However, Tanzanian law does not expressly codify a detailed Bolar-type regulatory review provision equivalent to those found in some jurisdictions. Below are few examples:

[31] Therefore, enforcement possibilities establish a link between the exhaustion doctrine and the issues of parallel importation. Under the exhaustion doctrine, once a patent-protected article, i.e a patented product or a product made by a patented process, has been put on the market by the right holder or with his consent, the patent owner's rights in respect of that product are terminated with the effect of assuring free circulation of products.
[32] WTO, *Agreement on Trade-Related Aspects of Intellectual Property Rights* (1994) Art. 30, p. 327
[33] WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (17 March 2000) paras 7.45–7.83, pp. 167–173.
[34] Cap. 217 R.E. 2023.
[35] S. 35.

(a) United States

35 U.S.C. § 271(e)(1)

The U.S. Bolar provision states:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention… solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs…

(b) European Union

Directive 2004/27/EC (amending Directive 2001/83/EC), Article 10(6)

The EU Bolar clause whose implementation occurs through national legislation of each Member State provides:

> Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights…

(c) India

Section 107A(a), Patents Act 1970 (as amended 2005)

India's provision is considered one of the most expansive codifications of the Bolar exception states:

> Any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law… in India or in a country other than India… shall not be considered as infringement of patent rights.

Thus, the absence of explicit regulatory review language may create uncertainty

regarding pre-expiry testing for marketing authorization of pharmaceuticals.

2.2.3.2. Research (Experimental Use) Exception

The research or experimental use exception allows third parties to use a patented invention for scientific research, experimentation, or teaching without infringing the patent. This exception is also grounded in Article 30 of the TRIPS Agreement, subject to the three-step test.[36] It is widely recognized as essential for promoting innovation and technological development. Its position in Tanzania rests on section 35 of the Patents Act, which limits the rights conferred by a patent by excluding acts done for scientific research or experimental purposes. This provision reflects compliance with TRIPS and preserves academic and non-commercial research activities. However, the scope of the exception, particularly whether it covers commercial research or regulatory testing, is not comprehensively clarified in statutory language or case law.

2.2.3.3. Utility Models

Utility models, also called petty patents or innovation patents, protect incremental or minor inventions that may not meet the higher inventiveness threshold required for standard patents. The TRIPS Agreement does not explicitly mandate protection for utility models, but Article 1.1 allows Members discretion in determining how to implement IP protection within their legal systems. Mainland Tanzania recognizes utility models under the Patents Act.[37] Utility model protection generally requires novelty and industrial applicability; imposes a lower inventive threshold compared to patents; and provides a shorter term of protection. Utility models are particularly significant for developing economies, as they encourage local, incremental innovation and small-scale technological improvements. In Tanzania's context, they may serve as a development-oriented tool supporting small and medium enterprises (SMEs) and informal sector innovation.

2.2.4. Control of Anti-Competitive Practices

The TRIPS Agreement recognizes that licensing practices may restrain competition and

[36] S. 35.
[37] See part II.

permits Members to adopt appropriate measures to prevent abuse of IP rights.[38] This reinforces domestic competition policy as a complementary regulatory tool. In Tanzania this is reflected by section 39 of the Patents Act.

2.2.5. Special and Differential Treatment

The TRIPS Agreement acknowledges developmental disparities among Members. In that acknowledgement, it granted developing countries transitional periods in terms of additional time to implement obligations.[39] It also provides Least Developed Countries (LDCs) with extended transition periods.[40] The WTO General Council has repeatedly extended the pharmaceutical transition period for LDCs, most recently until at least 2033.[41] These transition periods are core structural flexibilities embedded in the TRIPS Agreement.

2.3. The Doha Declaration on TRIPS and Public Health[42]

The 2001 Doha Declaration reaffirmed Members' rights to use TRIPS flexibilities to protect public health. Paragraph 4 states that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health.[43] Paragraph 5(b) further clarifies that each Member has the right to grant compulsory licenses and determine the grounds upon which they are granted. The Declaration is widely regarded as an authoritative interpretative instrument under Article 31(3)(a) of the Vienna Convention on the Law of Treaties.[44]

2.4. Jurisprudential Context

WTO dispute settlement bodies have played a role in clarifying the scope of flexibilities. For instance, in *Canada - Patent Protection of Pharmaceutical Products*,[45] a landmark dispute decided by the World Trade Organization (WTO) concerning the

[38] Art. 40.
[39] Art. 65.
[40] Art. 66.1.
[41] WTO General Council, *Extension of the Transition Period under Article 66.1 for LDC Members for Certain Obligations with respect to Pharmaceutical Products*, IP/C/88 (29 June 2021), p. 2.
[42] WT/MIN(01)/DEC/2 (14 November 2001).
[43] Para 4, p. 2.
[44] (Adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331.
[45] WT/DS114/R.

scope of patent exceptions under the TRIPS Agreement, the Panel emphasized that Article 30 exceptions must be carefully circumscribed but confirmed that regulatory review exceptions were valid.[46] This jurisprudence illustrates that flexibilities are legally structured, not unlimited, but nonetheless integral to the TRIPS Agreement.

2.5. Normative Character of TRIPS Flexibilities

TRIPS flexibilities are expressly embedded within treaty provisions that reflect a deliberate balance between private rights and public interest and operate within the constraints of WTO oversight and good faith treaty interpretation. They represent negotiated policy space rather than derogations from obligations.[21]

Therefore, the legal framework of the TRIPS flexibilities is multi-layered and treaty-based. It is grounded in the interpretative objectives and principles of Articles 7 and 8 of the TRIPS Agreement; substantive provisions such as Articles 6, 30, 31, 31bis, and 40 of the TRIPS Agreement; special and differential treatment under Articles 65 and 66 of the TRIPS Agreement; clarification through the Doha Declaration; and WTO jurisprudence. Together, these elements create a structured yet adaptable regime that permits WTO Members to reconcile intellectual property protection with public health, development, and competition objectives while remaining compliant with international trade law.

3. Applicability of TRIPS Flexibilities in Mainland Tanzania

The applicability of the TRIPS flexibilities in Mainland Tanzania must be understood within three interrelated legal layers, which are the Tanzania's status within the WTO system, the incorporation of TRIPS-consistent provisions in domestic legislation, and the practical regulatory environment governing intellectual property and public health.

3.1. WTO Membership and LDC Status

Tanzania has been a Member of the World Trade Organization (WTO) since 1995 and is classified as a Least Developed Country (LDC).[47] As an LDC, Tanzania benefits from extended transition periods under Article 66.1 of the TRIPS Agreement, which

[46] Para 7.26, p. 163.
[47] WTO, *Members and Observers – United Republic of Tanzania*. Available at www.wto.org. Accessed 20 February 2026.

allows delayed implementation of certain TRIPS obligations. In particular, WTO Members have repeatedly extended the pharmaceutical transition period for LDCs, most recently until at least 1 January 2033.[48] This means that Mainland Tanzania is not presently required to grant or enforce pharmaceutical product patents during the transition period, thereby preserving significant regulatory space for public health policy.

3.2. Incorporation into Domestic Law

The primary legislation governing patents in Mainland Tanzania is the Patents Act. The Act reflects TRIPS-consistent standards while preserving key flexibilities. Regarding compulsory licensing, the Act provides for compulsory licenses on grounds such as non-working of the patent; public interest; national emergency; and anti-competitive practices.[49] These provisions align with Article 31 of the TRIPS Agreement, which permits use of a patented invention without authorization of the right holder subject to specified safeguards.[6] Similarly, the Act allows government use of patented inventions in the public interest, including emergencies.[50]

This reflects Article 31(b) of the TRIPS Agreement, which waives prior negotiation requirements in cases of national emergency or public non-commercial use. To do with research (experimental use) exemption, the Act limits patent rights by excluding acts done for scientific research or experimental purposes.[51] This is consistent with Article 30 of the TRIPS Agreement, which permits limited exceptions to patent rights.[10] In respect of exhaustion and parallel imports, albeit not elaborately codified, the Act permits parallel importation under a regime compatible with Article 6 of the TRIPS Agreement, which leaves Members free to determine their exhaustion regime. The Doha Declaration further affirms Members' freedom to establish their own exhaustion policies.[52]

3.3. Article 31b is and Pharmaceutical Imports

[48] WTO General Council, *Extension of the Transition Period under Article 66.1 for LDC Members for Certain Obligations with respect to Pharmaceutical Products*, IP/C/88 (29 June 2021), p. 2.
[49] Ss. 37–41.
[50] S. 42.
[51] S. 35.
[52] Para 5(d).

As an LDC with limited pharmaceutical manufacturing capacity, Tanzania is eligible to use the Article 31bis TRIPS mechanism, which is also called the Paragraph 6 System, to import medicines produced under compulsory license in another country.[13] However, while this mechanism is legally available, domestic legislation does not expressly operationalize detailed procedures for invoking Article 31bis of the TRIPS Agreement, potentially limiting practical applicability.

3.4. Practical Applicability and Constraints

Although TRIPS flexibilities are legally available to Mainland Tanzania, their practical use is influenced by limited technical and administrative capacity; regulatory coordination challenges between IP and health authorities; market size and manufacturing constraints; and diplomatic and trade policy considerations. Thus, while Tanzania formally enjoys wide TRIPS-consistent policy space, particularly as an LDC, the operationalization of these flexibilities remains institutionally and economically constrained.

To say the list, the TRIPS flexibilities are fully applicable in Mainland Tanzania by virtue of its WTO and LDC status; the incorporation of compulsory licensing, government use, and research exceptions in the Patents Act; the freedom to determine exhaustion regimes under Article 6; and eligibility to utilize Article 31bis of the TRIPS Agreement for pharmaceutical imports. Nevertheless, the effectiveness of these flexibilities depends not only on formal legal incorporation but also on administrative capacity, regulatory clarity, and strategic public health policy.

4. Gaps in the Tanzanian Legal and Institutional Framework

This section examines the principal gaps under four dimensions, which are legislative drafting deficiencies, limited operationalization of compulsory licensing and Article 31bis of the TRIPS Agreement, institutional and administrative constraints, and systemic development challenges.

4.1. Legislative Gaps

4.1.1. Absence of Detailed Compulsory Licensing Regulations

The Patents Act provides for compulsory licenses on grounds such as public interest,

non-working, and anti-competitive conduct.[53] While these provisions reflect Article 31 of the TRIPS Agreement, they lack detailed implementing regulations addressing issues such as clear procedural timelines; royalty calculation methodologies; standards for determining adequate remuneration; and evidentiary requirements for establishing public interest or emergency. The TRIPS Agreement requires that right holders receive adequate remuneration in the circumstances of each case.[54] However, Tanzanian legislation does not define how such remuneration is to be calculated. The absence of structured guidelines may deter administrative authorities from invoking compulsory licenses due to uncertainty and litigation risks.

4.1.2. Limited Operationalization of Article 31bis (Paragraph 6 System)

As an LDC with limited pharmaceutical manufacturing capacity, Tanzania is eligible to use Article 31bis of the TRIPS Agreement, which allows importation of medicines produced under compulsory license elsewhere. However, there are several snags that hinder effective usage of this eligibility. Issues forming up these snags include the facts that the Patents Act does not expressly incorporate procedures for invoking Article 31bis; lack of detailed notification or anti-diversion mechanisms reflected in domestic regulations; and lack of instances that exist to evidence that Tanzania utilizing the Paragraph 6 System. The WTO General Council Decision incorporating Article 31bis establishes specific procedural requirements, including notification to the TRIPS Council and special labeling and packaging conditions.[55] The absence of domestic regulatory alignment with these procedures constitutes a structural gap.

4.1.3. Incomplete Codification of a Regulatory Review (Bolar) Exception

While the Patents Act excludes acts done for scientific research or experimental purposes,[56] it does not expressly codify a detailed Bolar-type regulatory review exception. In contrast, WTO jurisprudence in *Canada – Patent Protection of Pharmaceutical Products* confirmed that properly circumscribed regulatory review

[53] Ss. 37–41.
[54] Art. 31(h).
[55] WTO General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (8 December 2005), pp. 1–3.
[56] S. 35.

exceptions are consistent with Article 30 of the TRIPS Agreement.[57] The absence of explicit statutory language in Tanzania may create uncertainty regarding pre-expiry testing for pharmaceutical marketing approval. This gap may delay generic entry upon patent expiry, thereby indirectly affecting access to medicines.

4.1.4. Ambiguity in Exhaustion Regime

The TRIPS Agreement leaves Members free to determine their own exhaustion regime.[58] Although the Patents Act permits parallel importation in principle, the statutory framework does not clearly articulate whether the country follows a national, regional, or international exhaustion regime. The Doha Declaration on TRIPS and Public Health affirms Members' freedom to establish their own exhaustion regime.[59] However, lack of explicit codification may create interpretative uncertainty in enforcement contexts.

4.2. Institutional and Administrative Gaps

4.2.1. Capacity Constraints at the Business Registrations and Licensing Agency (BRELA) and Weak Inter-Ministerial Coordination

BRELA administers intellectual property rights in Mainland Tanzania. However, it faces several constraints such as technical expertise in complex TRIPS-based mechanisms, like compulsory licensing valuation models, remains limited; there is insufficient specialization in pharmaceutical patent examination; and budgetary constraints affect training and infrastructure. Effective implementation of the TRIPS flexibilities requires administrative competence, economic analysis, and regulatory coordination but here capacities mostly remain underdeveloped.

It also remains a clear fact that operationalizing the TRIPS flexibilities, particularly compulsory licensing, requires coordination between the Ministry of Industry and Trade, the Ministry of Health, drug regulatory authorities such as Tanzania Medicines

[57] WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (17 March 2000) paras 7.45–7.83, pp. 167–173.
[58] Art. 6.
[59] Para 5(d), p. 3.

and Medical Devices Authority (TMDA),[60] and the Attorney General's Chambers. However, institutional silos reduce responsiveness during public health emergencies. The Doha Declaration emphasizes the public health dimension of the TRIPS Agreement implementation,[61] yet domestic coordination mechanisms remain informal rather than structurally embedded.

4.2.2. Limited Judicial Specialization in IP Law

Although Tanzanian courts have jurisdiction over IP disputes, there is limited jurisprudence interpreting TRIPS-consistent provisions such as compulsory licensing or research exceptions. Judicial unfamiliarity with complex WTO law and the Article 30 three-step test may discourage administrative authorities from invoking flexibilities due to anticipated litigation risks.

4.3. Structural and Developmental Constraint

4.3.1. Limited Pharmaceutical Manufacturing Capacity

Even though Tanzania benefits from extended LDC transition periods under Article 66.1 of the TRIPS Agreement, the country has limited pharmaceutical manufacturing infrastructure. Thus, while compulsory licensing is legally available, practical production capacity constraints undermine its effectiveness unless Article 31bis of the TRIPS Agreement is operationalized.

4.3.2. Market Size and Economic Viability

Tanzania's relatively small pharmaceutical market may deter generic manufacturers from engaging in compulsory licensing arrangements due to limited commercial viability. As noted in development literature, the TRIPS flexibilities are most effective when supported by viable domestic or regional markets.[62] Without regional integration mechanisms, the economic incentive to utilize flexibilities remains weak.

[60] It was established under s. 4 of the Tanzania Medicines and Medical Devices Act, 2019 (Act No. 1 of 2019), which repealed and replaced the Tanzania Food, Drugs and Cosmetics Act, Cap. 219.
[61] Para 4, p. 2.
[62] UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press, 2005. Pp. 113–115.

4.3.3. External Pressures and TRIPS-Plus Risks

Developing countries may face diplomatic or trade pressures discouraging the use of compulsory licensing or parallel importation. While Tanzania is not heavily bound by the TRIPS-plus Agreements,[63] evolving bilateral trade negotiations may constrain policy space in the future.

Ultimately, although Mainland Tanzania formally enjoys extensive the TRIPS flexibilities, particularly as an LDC, the legal and institutional framework reveals notable gaps which include absence of detailed procedural regulations for compulsory licensing; lack of explicit operationalization of Article 31bis; incomplete codification of a regulatory review (Bolar) exception; ambiguity in exhaustion regime articulation; institutional capacity and coordination constraints; and structural economic limitations. All these gaps together do not eliminate the TRIPS flexibilities but significantly constrain their practical effectiveness. Addressing these deficiencies requires legislative refinement, institutional strengthening, and strategic integration of IP policy with national public health and industrial development strategies.

5. Comparative Lessons

Comparative experiences from Least Developed Countries (LDCs) demonstrate that while TRIPS flexibilities are legally available, their effectiveness depends on domestic legislative clarity, institutional capacity, and political commitment. Tanzania, as an LDC benefiting from extended transition periods under Article 66.1 of the TRIPS Agreement, can draw instructive lessons from other LDCs that have attempted to operationalize these mechanisms.

5.1. Bangladesh: Strategic Use of LDC Pharmaceutical Transition

It is reported that Bangladesh has actively utilized the LDC pharmaceutical transition period to expand domestic generic pharmaceutical production.[64] By delaying enforcement of pharmaceutical product patents, Bangladesh developed a competitive

[63] TRIPS-plus agreements are trade agreements (usually bilateral or regional free trade agreements) that require intellectual property (IP) protection standards higher or more extensive than those required under the TRIPS Agreement.
[64] UNCTAD, *The Least Developed Countries Report 2011,* United Nations, 2011. Pp. 118–120.

local industry capable of exporting medicines to other LDCs under the Article 66.1 transition framework.[65]While Tanzania benefits from the same transition period, its domestic pharmaceutical manufacturing base remains comparatively limited. The Bangladeshi model illustrates the importance of aligning industrial policy with the TRIPS Agreement transition advantages.

5.2. Rwanda: Use of the Paragraph 6 System (Article 31bis)

It is on record that Rwanda became the first country to use the WTO Paragraph 6 System, which is now Article 31bis of the TRIPS Agreement, to import antiretroviral medicines manufactured under compulsory license in Canada.[66] The process, however, revealed procedural complexity, including WTO notifications, quantity limitations, and special labeling requirements.[67]Although Article 31bis of the TRIPS Agreement is legally available, its administrative burdens require strong institutional coordination. Tanzania would need clear domestic procedures and regulatory preparedness to invoke the mechanism effectively.

5.3. Zambia and Malawi: Legislative Incorporation of Public Health Safeguards

Several African LDCs, including Zambia and Malawi, have incorporated broad compulsory licensing and government-use provisions in their national patent legislation consistent with Article 31 of the TRIPS Agreement.[68] However, actual invocation has been rare due to technical capacity and market constraints. Formal incorporation of the TRIPS flexibilities is insufficient without operational regulations, royalty guidelines, and institutional expertise.

5.4. Cross-Cutting Comparative Insights for Tanzania

If one is to do a comparative study on LDC experience and give opinion, it would in summary reveals five major lessons as follows:

---

[65] Ibid., p. 121.
[66] WTO, *Notification under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration*, IP/N/9/RWA/1 (19 July 2007). P. 1.
[67] WTO, *Amendment of the TRIPS Agreement*, WT/L/641 (8 December 2005). Pp. 1–3.
[68] UNCTAD-ICTSD, *Resource Book on TRIPS and Development,* Cambridge University Press, 2005. Pp. 113–115.

5.4.1 Industrial Policy Integration: Transition periods are most effective when linked to domestic pharmaceutical development (Bangladesh model).

5.4.2 Procedural Readiness: Article 31bis requires advance legal and administrative preparation (Rwanda experience).

5.4.3 Regulatory Clarity: Detailed implementing regulations improve certainty and confidence in compulsory licensing.

5.4.4 Regional Cooperation: Pooling markets through regional bodies enhances economic viability.

5.4.5 Capacity Building: Technical training for patent offices, health regulators, and judiciary is essential.

Eventually, Tanzania shares many structural similarities with other LDCs regarding the TRIPS flexibilities. Comparative experiences demonstrate that legal entitlement alone does not guarantee effective use; institutional capacity and industrial policy alignment are decisive; procedural complexity can deter invocation; and strategic planning is necessary to transform treaty flexibilities into practical development tools. These lessons underscore that closing the gap between formal applicability and effective utilization of TRIPS flexibilities in Tanzania requires coordinated legal reform, institutional strengthening, and integration of IP policy with public health and industrial strategies.

6. Recommendations

6.1. Enact Comprehensive Implementing Regulations for TRIPS Flexibilities

Mainland Tanzania should adopt detailed implementing regulations under the Patents Act to operationalize compulsory licensing, government use, Article 31bis of the TRIPS procedures, and regulatory review (Bolar) exceptions. The rationale for this recommendation is that although the Patents Act incorporates compulsory licensing[69] and research exceptions,[70] it lacks clear procedural timelines for compulsory license

[69] Ss. 37–41.
[70] Ss. 37–41 and s. 35 respectively.

applications; transparent royalty calculation guidelines consistent with Article 31(h) of the TRIPS Agreement; express codification of a regulatory review (Bolar) exception; and detailed procedures for invoking Article 31bis of the TRIPS Agreement (Paragraph 6 System). Without structured regulations, legal uncertainty and administrative hesitation undermine practical utilization.

To achieve this, there may be adopted subsidiary legislation defining "adequate remuneration" using internationally recognized royalty frameworks; codify an express Bolar-type regulatory review clause; incorporate clear procedures for WTO notification under Article 31bis of the TRIPS Agreement; and clarify the exhaustion regime to explicitly permit international parallel importation. Achieving this would reduce litigation risk, increase administrative confidence, and transform the TRIPS flexibilities from theoretical rights into operational tools.

6.2. Establish a Coordinated National TRIPS–Public Health Task Force

It is imperative to create a permanent inter-ministerial coordination mechanism linking BRELA (patent authority), Tanzania Medicines and Medical Devices Authority (TMDA), Ministry of Health, Ministry of Industry and Trade, and Attorney General's Chambers. Doing this would ensure effective use of the TRIPS flexibilities, particularly compulsory licensing and Article 31bis of the TRIPS Agreement, since such effectiveness requires synchronized legal, health, and trade decision-making. Current institutional silos delay response during public health emergencies.

Comparative experience, e.g., Rwanda's use of the Paragraph 6 System, demonstrates that procedural preparedness and institutional coordination are decisive. To achieve this, it is important to develop a national protocol for emergency invocation of compulsory licenses; conduct simulation exercises for Article 31bis procedures; train judicial officers and regulators in WTO/TRIPS jurisprudence; and integrate IP policy into national health security planning. This would enhance improved responsiveness during public health crises and enhanced legal preparedness.

6.3. Align TRIPS Flexibilities with Industrial and Regional Development Strategy

Tanzania should integrate the TRIPS flexibilities into a broader pharmaceutical and

industrial development strategy, including regional cooperation within the East African Community (EAC). The rationale for this is the fact that legal flexibilities are most effective when supported by manufacturing capacity and market viability. Bangladesh's experience as an LDC demonstrates how strategic use of transition periods can strengthen domestic pharmaceutical production. Tanzania's small domestic market limits commercial incentives for compulsory licensing unless complemented by regional pooled procurement, cross-border pharmaceutical trade, and local production incentives.

This can be achieved by providing fiscal incentives for domestic generic manufacturers; promoting public–private partnerships in pharmaceutical production; utilizing EAC frameworks to expand market size; and link the TRIPS Agreement transition advantages (Article 66.1) to industrial policy objectives. Having this in place would enhanced sustainability of access-to-medicines strategies and reduced dependency on imports.

For Mainland Tanzania, the challenge is not the absence of the TRIPS flexibilities, but the gap between formal legal availability and practical operationalization. Strong legislative refinement, institutional coordination, and strategic industrial alignment are essential to ensure that the TRIPS flexibilities function as effective instruments of public health and development policy rather than dormant treaty provisions.

7. Conclusion

TRIPS flexibilities offer Mainland Tanzania significant legal tools to balance intellectual property protection with public health and development objectives. While the legal framework formally accommodates these flexibilities, practical, procedural, and institutional constraints limit their effective use. Bridging these gaps requires legislative refinement, institutional capacity building, and strategic regional engagement. If effectively navigated, the TRIPS flexibilities can support Tanzania's long-term socio-economic and public health goals while remaining compliant with international trade obligations.