Journal of Contemporary African Legal Studies (JCALS)
2025, Vol. 2, No. 1, 107-122
DOI: 10.70564/jcals.v2i1.88

Faculty of Law

Enhancing Public Health in Tanzania: Underutilised Opportunities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Frank Mchomvu*

*Lecturer, Department of Public Law, Mzumbe University, Tanzania

Abstract

Using a doctrinal legal research approach, this paper analyzes the legal framework governing patents in Tanzania to evaluate its effectiveness in leveraging the opportunities provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to support public health. The findings reveal that Tanzania does not fully capitalize on the public health-related flexibilities within the TRIPS Agreement. Notably, it omits key public health-sensitive flexibilities, such as the transitional period and the Bolar exception, which are critical for promoting public health. The paper highlights that Tanzania undermines its public health interests by failing to fully exploit the relevant TRIPS flexibilities. Therefore, it is recommended that Tanzania seize the opportunities presented by the TRIPS Agreement by temporarily excluding medicines from patent protection while developing comprehensive patent legislation that incorporates all available options relevant to public health concerns.

Article History
Received: 20 February 2025
Accepted: 06 May 2025

Keywords:
Bolar Exception, Intellectual Property, Patent, Public Health, TRIPS Flexibilities

1. INTRODUCTION

A patent is a right granted to inventors, allowing them to exclusively exploit their invention for a specified period of time.[1] Patents provide inventors with legal protection for their creations while benefiting society by granting public access to technical details of these inventions, thereby accelerating innovation.[2] However, granting patents on medicines is increasingly recognised as a factor that jeopardises the realisation of the right to health by limiting access to affordable medicines.[3] This is based on the understanding that patents can create monopolies, limit competition, and allow patent holders to charge higher prices, thus restricting the ability of low-income individuals to obtain essential medicines.[4] Like many other rights, patent rights are not absolute and can be limited when necessary.[5]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) provides minimum intellectual property (IP) protection standards for its Members.[6] In this regard, it clearly states that Members are not required to provide protections that exceed those outlined in the Agreement within their domestic laws.[7] The Agreement also enables Members to decide how to incorporate its provisions into domestic laws and practices.[8] This freedom allows members to apply the Agreement's provisions in various ways, legislate in areas not bound by the minimum standards outlined, and form legal interpretations to ascertain the scope and content of the relevant obligations.[9] On this basis, Members may adopt flexibilities to ensure the balance between IP protection and other social, economic, and public interests.[10]

TRIPS Flexibilities refer to various legislative choices permitted under the TRIPS Agreement.[11] It includes the waiver available to least developed countries (LDCs) and the different interpretations and implementations of the TRIPS Agreement's provisions as they apply to the countries concerned.[12] The right of Members of the World Trade Organization (WTO) to utilise TRIPS flexibilities in protecting public health was notably recognised in the Declaration on the TRIPS and Public Health (Doha Declaration).[13] In this connection, the Doha Declaration clearly states that the TRIPS Agreement does not prevent WTO Members from taking measures to protect public health.[14]

---

[1] World Intellectual Property Organization 'What is a patent' available at https://www.wipo.int/en/web/patents [accessed 11 April 2025].

[2] *Ibid*.

[3] Motari M *et al* (2021) 'The Role of Intellectual Property Rights in Access to Medicines in the WHO African Region: 25 Years After the TRIPS Agreement' 21 *BMC Public Health* available at 1 https://doi.org/10.1186/s12889-021-10374-y [accessed 2 April 2025]. For details on the impact of intellectual property rights on access to medicines, see Tenni B *et al* (2022) 'What is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review 18 *Global Health* available at https://doi.org/10.1186/s12992-022-00826-4 [accessed 2 April 2025].

[4] World Health Organisation (2010) 'Intellectual Property and Access to Medicines: Papers and Perspectives' at 198 available at https://www.southcentre.int/wp-content/uploads/2016/05/Bk_2013_IP-and-Access-to-Medicines_EN.pdf [accessed 11 April 2025]. See also Ben K. Twinomugisha, Fundamentals of Health Law in Uganda (Pretoria: Pretoria University Law Press, 2015) 57. See also Brewster R (2011) 'The Surprising Benefits to Developing Countries of Linking International Trade and Intellectual Property' 12 (1) Chicago Journal of International Law 2 – 58 at 3.

[5] Correa CM (2020) 'Guide for the granting of compulsory licenses and government use of pharmaceutical patents' Research *Paper No. 107* South Centre: Geneva at 13 available at https://hdl.handle.net/10419/232227 [accessed 17 April 20205].

[6] World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property, Marrakesh, April 15, 1994, TRT/WTO01/001.

[7] Article 1(1).

[8] *Ibid*.

[9] Correa C. M (2022) 'Interpreting the Flexibilities Under the TRIPS Agreement' in Correa C M & Hilty R M (Eds) *Access to Medicines and Vaccines* Springer, Cham at 2 available at https://doi.org/10.1007/978-3-030-83114-1_12 [accessed 15 April 2025].

[10] Dos Santos F *et al* (2022) 'Intellectual property framework responses to health emergencies – options for Africa' 118(5/6) *S Afr J Sci.* https://doi.org/10.17159:// doi.org/10.17159/sajs.2022/12775 at 2.

[11] Correa (note 7) at 3.

[12] *Ibid*.

[13] DOHA WTO Ministerial 2001: TRIPS WT/MIN(01)/DEC/2 available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [accessed 15 April 2025].

[14] Paragraph 4.

As such, the Agreement should not be interpreted or applied in a way that undermines Members' right to protect public health, especially universal access to medicines.[15] Therefore, the Doha Declaration reaffirmed members' right to fully utilise the TRIPS provisions, which can potentially protect public health.[16]

Despite the potential of TRIPS flexibilities to minimise the negative impacts of patents on medicines and ensure public health protection, many African countries have not fully utilised these opportunities.[17] This situation restricts their ability to safeguard public health, particularly in providing essential medicines for all. While this paper does not argue that such flexibilities offer a complete solution to all the challenges posed by patents on public health, it maintains that, if appropriately utilised, these flexibilities are essential for protecting public health. However, the effectiveness of these flexibilities in supporting public health largely depends on how well they are integrated into domestic patent laws and how governments implement them. This is because such flexibilities are not self-executing.[18] As such, a country needs to enact specific provisions in its domestic law that enable it to utilise such flexibilities fully.[19]

This paper evaluates Tanzania's utilisation of public health-related TRIPS flexibilities to safeguard public health, focusing on ensuring universal access to medicines. To achieve this objective, it examines the legal framework governing patents in Tanzania to assess how effectively it incorporates the relevant public health flexibilities. The discussion is limited to four flexibilities: public non-commercial or government use, the Bolar exception, patentability criteria, and the transitional period.[20] The analysis highlights how Tanzania's patent law can strategically leverage TRIPS flexibilities while complying with the international IP standards established by the TRIPS Agreement, of which Tanzania is a member. Ultimately, the paper advocates for a more substantial commitment to effectively implementing these flexibilities to promote public health.

The paper employs a doctrinal legal research methodology known as black-letter law to achieve its objective. This method thoroughly analyses legal instruments to distil fundamental legal principles and doctrines. By doing so, the methodology deepens an understanding of the prevailing legal landscape and thoroughly addresses the study's objective. Consequently, the doctrinal legal research methodology is ideally suited to advance the primary aim of this paper.

2. BACKGROUND AND CONTEXT

The TRIPS Agreement was established as an essential element of the broader World Trade Organization (WTO) framework during the extensive Uruguay Round of negotiations from 1986 to 1994.[21] The primary motivation for introducing the TRIPS Agreement was the increasing recognition of IP's crucial role in promoting global trade and encouraging economic development.[22] Before the TRIPS Agreement was adopted, the international landscape was characterised by a significant lack of standardised IP protection.[23] This led to

[15] *Ibid.*
[16] *Ibid.*
[17] Nkomo M (2010) 'The Under-Utilization: The Case of Africa of TRIPS Flexibilities by Developing Countries, Research Papers From the WIPO-WTO Colloquium for Teachers of Intellectual Property at 125 available at https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2010/2010_complete_file_e.pdf [accessed 11 April 2025].
[18] *Ibid* at 126.
[19] *Ibid.*

[20] This paper does not discuss compulsory licenses and parallel imports, as the author has already addressed these topics in another paper. See Mchomvu F (2017) 'Compulsory Licensing and Parallel Imports under the Patent Legal Regime and their Implication on Access to Medicines in Tanzania' (2) 1 LST Law Review.
[21] World Trade Organization 'Intellectual property: protection and enforcement' available at https://www.wto.org/english/theWTO_e/whatis_e/tif_e/agrm7_e.htm [accessed 10 April 2025].
[22] *Ibid.*
[23] Mukherjee S (2023) Patent Exhaustion and International Trade Regulation Leiden: Koninklijke Brill NV at 116 – 117 available at

pronounced disparities in how countries recognised and enforced these rights.[24] Developed countries, led by the United States (US), advocated for adopting global standards for IP protection, arguing that this would promote innovation, attract foreign direct investment, and facilitate technology transfer in developing nations.[25]

However, the introduction of the TRIPS Agreement was not without its controversies, particularly concerning its implications for developing nations.[26] Critics voiced concerns that stringent patent protections could significantly obstruct access to essential medicines and technology, disproportionately impacting economically disadvantaged populations.[27] To address these pressing apprehensions, the TRIPS Agreement incorporated specific flexibilities intended to empower Member countries to reconcile these global standards with their public health needs.[28] Notably, provisions were embedded that enable countries to issue compulsory licenses, allowing them to authorise the production of patented medicines without the patent holder's consent under circumstances of national emergency or extreme urgency.[29] This mechanism is especially vital for expanding access to life-saving medications within low and middle-income countries, where the exorbitant costs of patented drugs can create significant barriers.[30]

In addition to compulsory licensing, the TRIPS Agreement recognises the necessity of safeguarding public health by allowing parallel imports. This method permits the importation of patented products from jurisdictions where they are sold at lower prices, enabling countries to harness price differentials in international markets, thus making essential medications more affordable for their populations.[31] Other flexibilities the TRIPS Agreement allows are patentability criteria, the Bolar exemption and the transitional period.[32]

Moreover, as noted above, the Doha Declaration significantly affirms WTO Members' rights to protect public health and enhance access to medicines for all. This pivotal Declaration underscores the flexibility afforded to countries to pursue measures that prioritise public health needs, even when they may conflict with strict enforcement of intellectual property rights. It emerged as a response to widespread concerns regarding the accessibility of essential medicines, particularly during global health crises, and emphasises the crucial interplay between IP and public health objectives.[33]

---

https://doi.org/10.1163/9789004542815_008 [accessed 10 April 2025].

[24] *Ibid* at 117.

[25] Correa CM (2005) 'The Trips Agreement and Developing Countries' in Macrory PFJ., Appleton AE & Plummer MG (Eds) The World Trade Organization: Legal, Economic and Political Analysis Boston, MA: Springer at 420 available at https://doi.org/10.1007/0-387-22688-5_54 [accessed 17 April 20205].

[26] *Ibid*.

[27] *Ibid* at 421.

[28] World Intellectual Property Organization 'Advice on Flexibilities under the TRIPS Agreement' available at https://www.wipo.int/ip-development/en/policy_legislative_assistance/advice_trips.html [accessed 11 April 2025].

[29] Article 31 of the TRIPS Agreement.

[30] See Vawda YA (2022) 'Compulsory Licenses and Government Use: Challenges and Opportunities in Correa C M & Hilty R M (Eds) *Access to Medicines and Vaccines* Springer, Cham available at https://doi.org/10.1007/978-3-030-83114-1_3 [accessed 11 April 2025]. For a detailed discussion on the legal position of compulsory licensing in Tanzania, see Mchomvu F (2017) 'Compulsory Licensing and Parallel Imports under the Patent Legal Regime and their Implication on Access to Medicines in Tanzania' (2) 1 *LST Law Review* 47 – 65 at 57 – 64.

[31] *Ibid* at 51. For a detailed discussion on this flexibility and its status under Tanzanian patent law, see pp 51 – 56.

[32] For additional details regarding the TRIPS flexibilities and their relevance to public health, see United Nations Development Programme (2010) Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement available at https://www.undp.org/sites/g/files/zskgke326/files/publications/Good%20Practice%20GuideImproving%20access%20to%20treatment%20by%20utilizing%20public%20health%20flexibilities%20in%20the%20WTO%20TRIPS%20agreement.pdf [accessed 11 April 2025].

[33] For details about the Declaration and its significance on public health, see generally Correa CM (2002) Implications of the Doha Declaration on the Trips Agreement and Public Health available at https://iris.who.int/bitstream/handle/10665/67345/WHO_EDM_PAR_2002.3.pdf?sequence=1&isAllowed=y [accessed 11 April 2025].

Therefore, TRIPS flexibilities, if effectively utilised, can play a significant role in supporting public health by minimising the negative impact of IP on medicines.[34] For instance, the flexibility to establish patentability criteria can ensure that patents are granted only for genuine innovations, resulting in fewer patents overall. Likewise, the power to determine the conditions under which compulsory licenses are issued enables governments to meet their human rights obligations by ensuring that health technologies remain accessible and affordable.[35]

In essence, the TRIPS Agreement establishes a framework for international IP protection. At the same time, the integrated flexibilities concerning public health serve as vital instruments that empower countries to navigate the complex landscape of health economics adeptly. These tools ensure that the benefits of innovation are distributed fairly and that the urgent public health needs of populations, particularly in developing nations, are effectively met.

3. OVERVIEW OF TANZANIA'S PATENT LAW

The Patent Registration Act (hereafter referred to as the Patent Act) establishes the framework for patent regulation in Tanzania.[36] This legislation is complemented by the Patent Regulations, which address various procedural aspects of the patent application and granting process.[37] The primary goal of the Patent Act is to enhance provisions that promote inventiveness and innovation while facilitating the fair acquisition of technology by granting and regulating patents, utility certificates, and innovation certificates.[38] Furthermore, the Act stipulates specific conditions under which patent rights can be exercised without the patent holder's consent, thereby balancing the interests of inventors and the public, such as compulsory licensing.[39]

Under the Patent Act, an invention is a novel solution to a distinct technical problem related to a physical product or a manufacturing process.[40] It is essential to understand that patents are generally granted for inventions rather than for medicines in a broad sense.[41] Consequently, patents can be awarded for: first, a specific chemical compound or molecule; second, a medical indication or therapeutic benefit linked to that molecule; third, a combination of products, such as a fixed-dose combination of two or more molecules; and finally, the manufacturing process itself.[42]

It is also worth noting that the definition of an invention under the Patent Act allows for patenting the end product and the techniques used to create it. This aligns with the TRIPS Agreement, which requires that patents be available for product and process inventions.[43] For instance, if an inventor secures a patent for a pharmaceutical product, they are afforded legal protection for the drug itself and the chemical compound employed in its production. This suggests that holding multiple patents for a single medicine is possible. Protection of both product and process hinders a third party from creating alternative medications through similar processes or employing different methodologies altogether.

The Patent Act further outlines specific categories of inventions excluded from patentability. These exclusions include discoveries of natural phenomena, scientific principles, and mathematical theories.[44] Additionally, the Act prohibits patenting plant or

[34] High-Level Panel on Access to Health Technologies (2016) *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines* at 7 available at https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf [accessed 11 April 2025].
[35] *Ibid.*
[36] Cap. 217 of the Laws of Tanzania.
[37] Government Notice Number 490 of 1994.
[38] See the long title of the Act.
[39] See part XI of the Patent Act.
[40] Section 7 (1).
[41] World Health Organisation (2008) 'Intellectual Property Rights and Access to Medicines: A South-East Asia perspective on global issues' at 9 available at https://iris.who.int/bitstream/handle/10665/205352/B3468.pdf?sequence=1&isAllowed=y [accessed 15 April 2025].
[42] *Ibid.*
[43] Article 27(1).
[44] Section 7(1) (a).

animal varieties and essential biological processes for producing plants or animals, except for microbiological processes and their resultant products.[45] Other excluded categories encompass business methods, abstract schemes or rules for conducting commercial activities, medical treatment methods involving surgery or therapy for human or animal bodies, and diagnostic methods.[46] However, products utilised in these processes remain eligible for patent protection.[47]

The rationale behind these exclusions is grounded in safeguarding foundational concepts within science and nature from privatisation.[48] By preventing individuals or entities from exercising control over fundamental natural laws or abstract ideas, the Patent Act aligns with broader ethical considerations in IP law, ensuring that essential scientific knowledge and natural resources remain accessible for the collective benefit of society. This approach not only promotes innovation but also aims to maintain a balance between private rights and public interests in the realm of scientific and technological advancement. This kind of exclusion is also permitted under the TRIPS Agreement.[49]

4. UTILISATION OF TRIPS FLEXIBILITIES IN TANZANIA'S PATENT LAW

This section examines the extent to which Tanzania's patent legal framework incorporates the flexibilities permitted under the TRIPS Agreement that are relevant to public health concerns. The analysis focuses on four key flexibilities: government use of patents, the Bolar exception, criteria for patentability, and the transitional period. Each of these flexibilities plays a crucial role in balancing the interests of patent holders with the urgent need for access to affordable medicines.

4.1. Government exploitation of patents

Government exploitation occurs when a government exploits a patented invention or authorises a third party to do so on its behalf without the patent holder's consent under prescribed circumstances.[50] This flexibility is enshrined in the Patent Act.[51] It can be utilised when an essential public interest needs to be addressed, particularly regarding national security, health, or the development of crucial sectors of the public economy.[52] When any specified conditions arise, the Patent Act allows the responsible Minister to authorise a government agency or a designated third party to exploit a patented invention, even without the patent holder's consent.[53] In this instance, the authorisation may encompass any rights granted to a patent holder, including making, importing, selling, using, or storing for purposes of selling.[54]

However, the Act requires that a patent holder be paid equitable remuneration following the exploitation of their invention.[55] It is essential to understand that the law does not grant the Minister the authority to make decisions in this situation solely based on personal judgment. Instead, the law establishes specific guidelines the Minister must follow before deciding. First, the minister must consult with the patent registrar, and second, a hearing must be convened, allowing the patent owner and any licensees to attend.[56] When deciding, the Minister must provide reasons and promptly send them to the patent registrar.[57] Once the decision is transmitted, the registrar is responsible for recording it in a special register, along with the reasons for the decision and

[45] Section 7(1) (b).
[46] Section 7(1) (c) & (d).
[47] *Ibid*.
[48] Mwakaje SJ (2012) 'Regulatory Framework of Intellectual Property Products: The Case of University Research and Patent Law in Tanzania' unpublished Ph. D thesis University of Dar es Salaam at 59.
[49] Article 27(2) & (3).
[50] Vawda (note 30) at 73. See also Correa (note 5).
[51] Section 62.
[52] Section 62 (1).
[53] *Ibid*.
[54] *Ibid.* About the rights of a patent holder, see Section 36 of the Patent Act.
[55] Section 62 (1) & (3).
[56] Section 62 (2).
[57] See Regulation 51 (1).

details regarding remuneration.[58] The Registrar of Patents has the authority to determine the amount of compensation payable after the Minister has decided that the patented invention will be exploited.[59] This remuneration must be fair and consider all relevant circumstances.[60] Payment of remuneration to the patent owner is in line with the TRIPS Agreement.[61]

While the Act provides that the patent owner and any licensee must be invited to a hearing, it does not explicitly clarify the purpose of that hearing. This paper argues that the requirement to hold a hearing before making such a decision constitutes an unnecessary procedural step. Although a hearing must be conducted, the patent owner or licensee has no legal right to approve the terms of use or consent to the decision to utilise their invention. The Patent Act merely requires that the Minister's decision be provided in writing, and that the patent owner and any parties heard be notified of the decision.[62] Even the TRPS Agreement does not require a hearing before utilising this flexibility. It only requires Members to notify the patent owner of the utilisation of their invention as soon as reasonably practicable.[63] Although the requirement for a hearing does not allow right-holders to contest the decision to utilise a patented invention, this paper contends that compelling a hearing before the use of a patented invention constitutes a TRIPS-plus measure, as it goes beyond the stipulations of the TRIPS Agreement. Furthermore, it is contradictory to require a hearing while simultaneously requiring the notification of the patent holder or any licensee regarding the decision to exploit the invention.

It is also worth noting that the Patent Act does not provide a provision for the patent owner to challenge the decision to exploit their invention in this situation. Instead, it allows a patent owner to challenge the decision relating to remuneration by filing an appeal to the High Court.[64] However, it is essential to note that even if the patent owner disputes the decision on remuneration, such an appeal does not impede the exploitation of the patented invention.[65] This is significant because legal proceedings often take considerable time to conclude. Allowing legal challenges to the decision to exploit a patented invention for the public interest, or suspending its implementation pending the outcome of an appeal, could delay the exploitation and undermine the intended flexibility. Such delays could adversely affect the public, particularly when the flexibility is invoked to address public health emergencies. From a public health perspective, prioritising immediate utilisation of the patented invention is justified, as it accelerates access to critical technologies during health crises. Although this approach may appear unfair from an intellectual property standpoint, it reflects a situation where public interest must take precedence over individual rights.

Furthermore, it is important to note that the Patent Act does not require the pursuit of a voluntary licence before invoking this flexibility. This position is consistent with the TRIPS Agreement, which permits Members to waive the voluntary licence requirement in cases of national emergencies, other extreme circumstances, or public non-commercial use of a patented invention.[66]

The government's use of patented inventions is pivotal for advancing public health in Tanzania. It can significantly enhance the accessibility and affordability of essential medicines during public health emergencies.[67] By adopting this strategic approach, the government can ensure that patented medicines are accessible to the public, particularly benefiting poor and marginalised populations who often face financial barriers to healthcare. This flexibility eliminates the need for complicated procedures, resulting in

[58] See Regulation 51 (2).
[59] Section 62 (3).
[60] Section 62 (3).
[61] Article 31 (h).
[62] Regulation 51 (1) & (2).
[63] Article 31 (b).
[64] Section 62 (4).
[65] Section 62 (4).
[66] See Article 31(b) of TRIPS Agreement.
[67] Vawda (note 30) at 87.

significant cost savings and time efficiency.[68] Therefore, when applied effectively, it can dramatically expand the country's access to affordable generic medicines, especially in crisis situations where urgent medical intervention is necessary. For instance, during health emergencies like disease outbreaks or natural disasters, this flexibility can save countless lives and prevent further deterioration of public health. Correa argues that the government might utilise patented inventions to distribute medicines in dispensaries, hospitals, and other medical facilities owned or operated on its behalf.[69]

However, despite the crucial role this flexibility could play in supporting public health initiatives, its potential remains significantly constrained in Tanzania, like in many LDCS. A significant hurdle in this respect is low technological capacity.[70] This low technology limits the manufacturing capacity of local pharmaceutical industries, which struggle to produce sufficient quantities of quality medicines that meet national needs. Furthermore, the political commitment to leverage this flexibility is often lacking, resulting in missed opportunities to enhance access to vital treatments.[71] As a result, this important strategic option has not been utilised in Tanzania, leaving many residents without access to essential medicines for their well-being. For the government to successfully harness this flexibility to improve health outcomes, it will need to invest in strengthening local pharmaceutical production capabilities and foster a stronger political will to prioritise public health initiatives.

4.2. Bolar exception

Some products, particularly pharmaceutical ones, must obtain approval from the relevant authorities before marketing.[72] Due to numerous factors, approval requirements vary by country, sector, or even within the same sector.[73] The practice of utilising a patented invention without the patent holder's consent to secure essential marketing approval for a generic product is commonly known as the early working of a patent or the Bolar exception.[74] This flexibility permits generic manufacturers to engage in specific activities related to developing and testing their products before the patent expires, facilitating competition and expediting access to affordable medications in the market.[75]

The term Bolar exception originated in 1984 from the US case of *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., 733 F.2d 858.*[76] The brief facts of this case indicate that Bolar Pharmaceuticals, a pharmaceutical company, sought to conduct the research required by the US drug regulatory authority to manufacture generic versions of a drug still under Roche's patent protection.[77] Roche, a considerable

[68] *Ibid* at 95. See also Correa (note 5) at 30.
[69] Correa (note 5) at 30.
[70] Adaji AE & Isa AS (2024) 'The Viability of Patent-Related Flexibilities in Promoting Biotechnology Research and Innovation for Improved Food Security and Public Health in Nigeria' 7 (1) *Redeemer's University Law Journal* at 14 available at https://www.runlawjournals.com/index.php/runlawj/article/view/79 [accessed 17 April 2025].
[71] *Ibid*.
[72] World Intellectual Property Organization (2017) 'Draft Reference Document on Exception Regarding acts for Obtaining Regulatory Approval from the Authorities' at 3 available at https://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_3.pdf [accessed 17 April 2025].
[73] *Ibid*.
[74] Correa CM (2001) 'Public Health and Patent Legislation in Developing Countries' 3 *Tulane Journal of Technology and Intellectual Property* at 36 available at https://journals.tulane.edu/TIP/issue/view/313 [accessed 17 April 2025].
[75] Tellez VM (2022) 'Bolar Exception' in Correa C M & Hilty R M (n 8) at 137 available at https://doi.org/10.1007/978-3-030-83114-1_5 (accessed 17 April 2025).
[76] World Intellectual Property Organization (2014) 'Facilitating generic drug manufacturing: Bolar exemptions worldwide' *WIPO Magazine* available at https://www.wipo.int/web/wipo-magazine/articles/facilitating-generic-drug-manufacturing-bolar-exemptions-worldwide-38860 [accessed 17 April 2025].
[77] This case is available at https://law.justia.com/cases/federal/appellate-courts/F2/733/858/459501/ [accessed 17 April 20205]. See also Doubinsky D (2025) 'Application of the Bolar

research-oriented pharmaceutical company, sued Bolar, alleging a violation of its patent rights. The District Court ruled in favour of Bolar, stating that the research was legal because it was not intended for commercial purposes. However, Roche appealed the decision to the Appellate Court, which reversed the District Court's ruling and upheld Roche's claims. The court determined that Bolar Pharmaceuticals could not use test data to gain market approval for generic drugs. Subsequently, the US passed the Hatch-Waxman Act, enabling the use of test data for market approval, which altered the previous position held by the District Court.[78]

Once the patent monopoly ends, the patent no longer serves as a legal barrier that prevents a competitor from manufacturing and selling the protected product or employing the protected process.[79] Nevertheless, other market challenges may still exist, including the requirement to comply with regulatory standards to obtain permission for market entry.[80] Regarding drugs, just like brand-name drug manufacturers, generic drug producers are also required to demonstrate the efficacy and effectiveness of their products.[81] As such, to obtain market approval, they must convince the regulatory authorities responsible for drug registration that their generic versions are as effective and safe as their branded counterparts.[82] They will be required to conduct clinical trials and tests to demonstrate the safety and effectiveness of the drug they wish to register.[83]

From an IP standpoint, using the data that the original inventor relied upon may constitute patent infringement.[84] This applies even if the generic manufacturers do not intend to sell their products until after the patent expires. To reduce the risk of patent infringement, generic manufacturers must wait until patent rights have expired before conducting the necessary tests for marketing approval. This requirement often leads to delayed market entry for competitive products, as obtaining marketing approval may take several years.[85]

To enable quick entry into the market for generic medicines, many countries have included a Bolar exception in their laws.[86] The specific provisions regarding Bolar exemptions may vary from country to country based on the prevailing circumstances.[87] The Bolar exception provisions have simplified the procedures for obtaining marketing approval for new drugs in countries that have included such an exception in their laws. For instance, the US Food and Drug Administration (FDA) does not require manufacturers to repeat preclinical and clinical studies to demonstrate the effectiveness and efficacy of a drug.[88] Instead, the FDA only requires generic drug producers to submit data that shows the generic product is bioequivalent to the patented version.[89] However, some

Exception: Different Approaches in the EU' *214 Research Paper* South Centre at 10 available at https://www.southcentre.int/wp-content/uploads/2025/01/RP214_Application-of-the-Bolar-Exception_EN-1.pdf [accessed 17 April 20205].

[78] Carlos M. Correa, The Bolar Exception: Legislative Models and Drafting Options' Research Paper 66 (South Centre) (March 2016) p. 2, available at https://www.southcentre.int/wp-content/uploads/2016/03/RP66_The-Bolar-Exception_EN1.pdf accessed 24 January 2025).

[79] Tellez (note 75) at 137.

[80] *Ibid*.

[81] See Canada's Drug Agency, 'Similarities and Differences Between Brand Name and Generic Drugs' available at https://www.cda-amc.ca/similarities-and-differences-between-brand-name-and-generic-drugs accessed 21 February 2025.

[82] Correa (note 25) 1-3.

[83] Anthony Tridico et al., 'Facilitating Generic Drug Manufacturing: Bolar Exemptions Worldwide' *WIPO Magazine*, (2014)3 available at https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html accessed 26 January 2025.

[84] World Intellectual Property Organization (note 76).

[85] *Ibid.* See also Correa (note 74).

[86] See, for example, the Patent Act of Canada, Section 55 2 (1). See also Section 107A of the Indian Patent Act, 1970.

[87] Ashok A 'Bolar Exemption as a Means for Easier Access to Medicine' (2022) *On Human Rights in Health Care* at 40 available at https://ssrn.com/abstract=4471556 [accessed 17 April 2025].

[88] Correa (note 25) p. 3.

[89] *Ibid*.

regulatory authorities do not always require proof of bioequivalence.[90]

In 1998, the WTO examined whether the TRIPS Agreement permits the Bolar exception in a case brought against Canada by the European Communities and their Member States.[91] Canadian patent law contained a provision that permitted third parties to use patented inventions to submit necessary information for market approval and to stockpile the product for up to six months, to be released immediately upon the expiration of the patent term.[92] The relevant provision in the Canadian Law reads:

> It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.[93]

The WTO concluded that Canada's provision regarding using patented information to obtain market approval did not infringe the TRIPS Agreement.[94] This is because it satisfies all three criteria described in Article 30, meaning that it constitutes a narrow exception that does not unreasonably obstruct the typical use of the patent and does not unjustly harm the rights of the patent owner while also considering the legitimate interests of third parties.[95] However, the WTO ruled that Canada violated the TRIPS Agreement by allowing the manufacturing and stockpiling of generic drugs while awaiting the expiration of the patent term because the practice did not satisfy the first test concerning limitations outlined in Article 30 of the TRIPS Agreement.[96]

To determine whether the Bolar exemption is included in Tanzania's patent legal framework, this article examines Section 38 of the Patent Act, which outlines general limitations on patent rights in Tanzania. The section specifies five exceptions under which patent rights do not apply. The first limitation states that the rights granted under a patent do not extend to actions taken for non-industrial and non-commercial purposes, meaning these rights do not cover activities conducted for scientific research. The second limitation restricts the applicability of patent rights to products that have been put on the market within the United Republic of Tanzania. The third limitation indicates that patent rights do not apply to the use of articles in aircraft, land vehicles, or vessels from another country that enter Tanzania accidentally or temporarily. The fourth limitation pertains to the patent duration outlined in the Patent Act. Finally, patent rights are limited by provisions related to compulsory licenses and the government's exploitation of the patented invention.

The limitations outlined above clearly indicate that the Bolar exception does not apply within Tanzania's legal framework. This conclusion is based on the fact that the specified limitations do not extend to circumstances involving the use of patented inventions to obtain marketing approval for generic drugs. Consequently, under Tanzanian law, patent holders retain the unequivocal right to restrict any third party from utilising their patented inventions to seek marketing authorisation for generic products.

This paper uses India as an example to illustrate how a provision on patent law could be incorporated into domestic law. The adoption of the TRIPS Agreement significantly impacted

[90] *Ibid.*
[91] World Trade Organisation, Canada — Patent Protection of Pharmaceutical Products' available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm [accessed 17 April 20205].
[92] See Section 55 (2) (1) of the Canadian Patent Act.
[93] Canada Patent Act Section 55.2(1).
[94] WTO (note 91).
[95] *Ibid.*
[96] *Ibid.*

India, leading to the inclusion of the Bolar exception in its patent legislation to improve access to affordable medicines. To facilitate this, India amended its Patent Act of 1970 in 2002, introducing specific provisions for the Bolar exemption. The relevant provision in Indian law 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 for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product; shall not be considered as an infringement of patent rights.[97]

The provision quoted above allows patented inventions to be used for development or submitting the required information to relevant authorities. This means that manufacturers of generic medicines can utilise the patented invention in the specified manner to obtain approval for their generic products. As a result, competitor products can enter the market as soon as the patent term expires.

Unfortunately, Tanzania's legal framework does not include this crucial exception, which is permitted under the TRIPS Agreement. This means that, unlike jurisdictions where the Bolar exception facilitates the market entry of generics before patent expiration, Tanzanian patent law does not offer similar provisions. In this way, the law in Tanzania safeguards the interests of patent owners by maintaining their control over the commercialisation of their inventions until the expiration of their patent rights. As a country that is both economically disadvantaged and facing serious health challenges, Tanzania could have benefited from incorporating this option into its laws to create a legal environment that supports public health, particularly access to medicines.

The inapplicability of this important exception in Tanzania means that if a medicine is patented in the country, anyone who wants to manufacture a generic version must wait for the patent to expire before they can use the information from the patented drug to obtain marketing approval from the relevant authority. The Bolar exception facilitates the entry of generics and biosimilars into the market by permitting manufacturers to develop these products prior to the expiration of the original patents.[98] Consequently, as previously indicated, this situation hinders the immediate entry of generic medicines into the market, even after the expired patent term. This is detrimental to public health, particularly regarding access to medicines. The introduction of generics typically reduces the prices of patented medications, which can result in the patent holder losing a significant portion of the market, potentially as much as half, depending on various factors, such as the number of generics available, the overall market size, and how easily the product can be copied.[99]

Additionally, the absence of a Bolar exception clause may suggest a *de facto* extension of the patent term.[100] This is because the patent holder will continue to enjoy exclusive rights even after the patent has expired. From a public health standpoint, this scenario is highly concerning as it may hamper access to affordable medicines for low-income individuals. In LDCs like Tanzania, where a significant portion of the population relies on inexpensive generic medications, the consequences can be particularly severe.

4.3. Patentability criteria

Under the Patent Act, an invention is considered patentable if it provides a solution to a specific problem.[101] This invention can be a product or a

[97] Section 107A (a).

[98] Tellez (note 75) at 141.

[99] Jayashree W (2014) 'Bolar Exception to Patent Rights: Some Economic Implications' *SCP Seminar on Exceptions and Limitations to Patent Rights,* at 4 available at http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_ref_watal.pdf. [accessed on 18 April 2025].

[100] World Intellectual Property Organization (note 72) at 4. See also Tellez (note 75).

[101] Section 7(1).

manufacturing process. Three criteria must be met for an invention to be regarded as patentable in Tanzania: novelty, inventive step, and industrial applicability.[102]

The term novelty refers to something being new. For an invention to be considered patentable in Tanzania, it must meet this newness criterion. However, this determination is not arbitrary; the law provides specific standards for assessing novelty. According to the Patent Act, an invention is regarded as new only if it is not 'anticipated by prior art.'[103] The prior art includes everything made publicly available anywhere in the world.[104] This can include written materials, drawings, illustrations, oral disclosures, use, exhibitions, or other unwritten means. For a piece of information to be classified as publicly available, it must have been accessible to the public before a patent application is filed or, if a priority claim is made, before the valid priority date of that claim.[105] The priority date is 'the filing date of an earlier application that serves as the basis for the right of priority.'[106] When evaluating the novelty criterion, any patent application will be considered part of the prior art if its contents are made public according to the provisions of the Patent Act or the Patent Cooperation Treaty (PCT).[107]

The requirement of newness is crucial for patentability, as it prevents knowledge already in the public domain from being subjected to a statutory monopoly. This raises ethical concerns and may undermine the fundamental purpose of patent protection. The concept of novelty can be understood from two perspectives, namely, a narrow perspective and a broader perspective, which can be distinguished as 'relative novelty' and 'absolute novelty.'[108] Relative novelty refers to situations where the invention exists only in the specific country seeking the patent, whereas absolute novelty pertains to inventions that exist anywhere in the world.[109] Stricter criteria like absolute novelty are beneficial for establishing stringent standards for patentability, which can promote access to medicines. Consequently, in terms of improving public health, absolute novelty emerges as the preferable approach.

It is important to emphasise that the TRIPS Agreement does not define novelty. This absence allows Members the flexibility to define what constitutes novelty on their terms without violating TRIPS obligations. Consequently, these countries have broader discretion in establishing their standards for patentability, taking into consideration their specific policy priorities. This flexibility is a significant aspect of the international IP framework that members can leverage to enforce stringent criteria for patentability, thereby encouraging authentic innovation. Additionally, for certain countries, the prevalence of patent applications originating from abroad serves as a motivation to impose stricter patentability standards.[110]

The second criterion for granting a patent for an invention in Tanzania is that the invention must demonstrate an inventive step. This means that the invention must pass the non-obviousness test; in other words, it should be more than just obvious. According to the Patent Act, an invention is considered to have an inventive step if, after considering prior art, it would not have been obvious to a person skilled in the art on the date of applying or, if priority is claimed, on the valid priority date claimed.[111]

Similar to the novelty requirement, the TRIPS Agreement does not define the concept of inventiveness, allowing each member to establish its criteria for what constitutes an

[102] Section 8.
[103] Section 9 (1).
[104] Section 9 (2).
[105] *Ibid*. On the right of priority, see Section 21 of the Act.
[106] Patent Regulations, Regulation 2 (1).
[107] Section 9 (3) of the Patent Act.
[108] Park C *et al* (2013) 'Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law' New York: United Nations Development Program at 26 available at https://www.undp.org/sites/g/files/zskgke326/files/publications/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf [accessed 17 April 2025].
[109] *Ibid.*
[110] *Ibid.*
[111] Section 10.

inventive step. This flexibility is crucial as it enables members to set standards of obviousness that reflect local circumstances.[112] Consequently, domestic courts have greater discretion when interpreting and applying this criterion in disputes. Furthermore, this flexibility allows countries to impose different levels of patent protection for the same product by establishing varying criteria for inventiveness. In relation to public health, this could discourage patents on essential medications by adopting a strict definition of what qualifies as an inventive step in the context of pharmaceuticals. Additionally, it provides the opportunity to exclude certain new methods of using existing products from patentability.

For an invention to be patentable in Tanzania, it must not only be novel and involve an inventive step but also have industrial applicability. This means that an invention is patentable only if it is useful or can be applied in industry. According to the Patent Act, an invention is considered to have industrial application if, given its nature, it can be used or manufactured in various industries, including agriculture, fisheries, and services.[113] In summary, the invention must be capable of practical use in an industrial setting.

The usefulness of an invention is a critical criterion for patentability, much like the other two criteria. This requirement ensures that patented inventions contribute to societal development and provide tangible benefits to the public. In essence, it prevents patents from being granted for inventions that are deemed useless or that do not serve the general public interest, as such practices would undermine the fundamental purpose of the patent system. In the context of access to medicines, one could argue that this principle reinforces the notion that patented inventions, particularly pharmaceuticals, should be accessible to the public.

It is important to note that, Tanzanian law permits the grant of patents for inventions, even if their exploitation is restricted by law.[114] However, such patents will not be granted if their exploitation is deemed contrary to public order or morality.[115] This implies that public order and morality considerations take precedence over legal provisions in determining the exploitation of patented inventions.

Furthermore, the law establishes a time limit for disclosing an invention subject to patenting. Specifically, it stipulates that for the disclosure to be considered valid, it must occur no earlier than six months before the filing date.[116] Consequently, an individual claiming to be an inventor of a particular product or process must demonstrate that the invention has existed for at least six months from the date the application was submitted.

It is also important to highlight that under the Patent Act, there are specific circumstances in which the patentability of certain products or processes for manufacturing them may be temporarily excluded through a statutory instrument for up to ten years.[117] In this context, it can be argued that this provision may positively impact access to medicines in Tanzania. Relevant authorities could potentially utilise this option to postpone the registration of patents on essential drugs for a designated timeframe. Such a delay might allow generic manufacturers to produce patented medications without having to navigate the complex procedures typically associated with obtaining a compulsory licence, for example. However, it is important to note that this approach may encounter challenges, as it could be perceived as a violation of Article 30 of the TRIPS Agreement for potentially undermining the legitimate interests of inventors.

[112] United Nations Economic Commission for Africa (2018) 'Developing an intellectual property rights framework in the Southern African Development Community' at 41 available at https://archive.uneca.org/sites/default/files/PublicationFiles/e1700855_developing_an_intellectual_property_rights_framework_in_the_southern_african_development_community.pdf [accessed 21 February 2025].

[113] Section 11.

[114] Section 12.

[115] *Ibid.*

[116] Section 9 (4).

[117] Section 13.

It is essential to recognise that the provisions regarding patentable inventions outlined in Section 8 of the Patent Act closely align with Article 27(1) of the TRIPS Agreement, which delineates the same criteria for granting patents. Therefore, it can be concluded that the Patent Act complies with TRIPS standards concerning the criteria for patentability. The criteria for patentability represent a significant yet often overlooked flexibility in promoting public health. This approach can serve as a strategy to mitigate the effects of patents on public health when the option to eliminate a patent is not viable. Consequently, countries must establish stringent patentability criteria within their domestic laws to discourage the issuance of trivial patents, particularly concerning medicines. In essence, rigorous patentability standards enhance the capacity to exclude simple patents.

Implementing stringent criteria for patentability is crucial within the patent system to promote access to medicines. This approach will result in the grant of fewer patents since many will not meet the established criteria. With fewer patents, particularly on medications, there will be increased competition from generic drug manufacturers. This competition will likely drive down drug prices and ensure a reliable supply of medicines, as there will be multiple producers in the market.[118] This is why it is important to adopt strict patentability criteria to enhance access to medicines.

Imposing stringent criteria for patentability will also create genuine incentives for research and development (R&D).[119] On the other hand, adopting a narrow definition of novelty could enable patent applicants to manipulate existing inventions, presenting their claims as distinct from what already exists. This could be particularly concerning in the pharmaceutical sector, where it might allow for older medicines to be reclassified in a manner that meets the novelty requirement, despite not being substantially different from already available substances.[120]

Having established the significance of strict criteria for patentability, it is now pertinent to discuss the legal framework in Tanzania. The Patent Act defines novelty in a manner that emphasises absolute novelty. Specifically, it stipulates that for an invention not to be considered anticipated by prior art, it must not have been publicly disclosed anywhere in the world. Consequently, the mere fact that an invention has not been made public in Tanzania or even within Africa before the patent application does not render it novel for patentability purposes. It must be demonstrated that the invention has not been publicly disclosed anywhere globally. Therefore, if evidence shows that the invention has been made publicly available in any country around the world, it cannot be classified as new. This stringent criterion for novelty effectively discourages the granting of simple patents. As noted, this approach aligns with public health interests by preventing the patenting of straightforward innovations.

In light of the preceding points, this paper argues that the criteria for establishing novelty as outlined in the Patent Act of Tanzania provide a reasonable framework for defining what should be considered novel in the context of patent granting. This definition represents an absolute standard of novelty that is particularly beneficial for promoting public health, especially in terms of enhancing access to medicines. If effectively utilised, this flexibility can reduce patents in medicine. Fewer patents on drugs increase the availability of affordable generics, promoting access for all.

A pertinent example of how novelty, as a criterion for patentability, can be leveraged to advance public health is illustrated by the case of *Novartis AG v. Union of India & Ors*.[121] The

[118] Park (note 108) at 26.
[119] *Ibid*.

[120] *Ibid* at 28.
[121] *Novartis Ag v. Union of India & Ors* Civil Appeal Nos. 2706-2716 [2013] (Arising out of SLP (C) Nos. 20539-20549 [2009].

central issue addressed by the Supreme Court of India was whether the appellant was entitled to patent protection for a drug known as *Beta Crystalline*, a form of *Imatinib Mesylate*. To resolve this question, the Court needed to ascertain whether the invention in question met the novelty requirement outlined in the Indian Patent Act of 1970. The Patent Office had initially rejected the application because the product did not fulfill the novelty criteria. Novartis, dissatisfied with this outcome, appealed to the Madras High Court, which subsequently transferred the case to the Intellectual Property Appellate Board. The Board concluded that while the invention met the criteria for novelty and non-obviousness, it could not be patented because it was merely an amended form of an existing substance. Furthermore, Novartis had not demonstrated the requisite increased efficacy of the product as mandated under Section 3(d) of the Indian Patent Act. Undeterred, Novartis appealed to the Supreme Court, contesting the Appellate Board's decision. Ultimately, the Supreme Court dismissed the appeal with costs, determining that the product not only failed to satisfy the novelty requirement but also did not meet the efficacy standards outlined in Sections 2(1) (j) (a) and 3(d) of the Indian Patent Act.

4.4. Transition period

As previously mentioned, LDCs are generally not required to grant patents for pharmaceutical products. The TRIPS Agreement initially provided a waiver to Members from LDCs for 10 years from 1995 with a possibility of extension.[122] This was done with the understanding that LDC Member States face economic, financial, and administrative challenges and the need for flexibility to establish a viable technological base.[123] Since then, the transition period has been extended three times, with the latest extension occurring in 2021, which prolonged the waiver until 1 July 2034.[124]

Despite this waiver, it is important to note that inventions related to medicines continue to be fully patentable in Tanzania. This is surprising, particularly as this year marks the thirtieth anniversary of the TRIPS Agreement, which, as indicated above, has had its transitional period extended multiple times. While Tanzania Mainland has not utilised the transitional period regarding pharmaceutical products, Zanzibar has fully embraced this flexibility. It has enacted a provision that explicitly excludes medicines from patentable inventions until the transitional period expires.[125]

The utilisation of the transition period to withhold patents on medicines is significant for public health. The lack of patents on pharmaceutical products allows local pharmaceutical companies to produce affordable generics without infringing any patent and without undergoing a complex procedure of invoking other flexibilities such as compulsory licence. This situation can foster the growth of generic industries in the country, thereby strengthening the local pharmaceutical sector. As a result, public health can be positively impacted, as these industries will not need to wait for the expiration of patent terms before they can legally manufacture generics. The production of these generics will likely drive down medicine prices, enabling a more significant segment of the population, particularly those with lower incomes, to access affordable yet quality medications.

In contrast, the existing law does not appeal to generic manufacturers. It prohibits the production of patented drugs until after the expiration of the patent term, except under specific exceptions recognised by the law. This limitation effectively restricts the ability of generic manufacturers to produce generics, as they are primarily allowed to work with

[122] Article 66 (1).
[123] *Ibid*.
[124] World Trade Organization 'Responding to least developed countries' special needs in intellectual property' available at https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm#:~:text=Transition%20period%20extension%20under%20TRIPS%20Article%2066.1&text=Most%20recently%2C%20on%2029%20June,if%20that%20happens%20before%202034 [accessed on 18 April 2025].
[125] See Section 3(1) (x) of the Zanzibar Industrial Property Act, 2008.

medicines whose patent terms have already lapsed.[126]

The preceding discussion demonstrates that utilising the transition period as an exception within the patent legal framework significantly supports public health by improving access to medications for all. Therefore, it is crucial for Tanzania to effectively leverage the transition period to enhance public health within the country. Although this flexibility is time-limited, a well-utilised transition period has the potential to alleviate the impact of patents on medicines for a specified duration, allowing Tanzania the necessary time to establish a robust patent law that aligns with health needs. Furthermore, it is essential to highlight that several LDCs, including those in the East African Community (EAC), have successfully taken advantage of the transition period, with Uganda, Rwanda, and Burundi being notable examples of countries that have amended their laws accordingly.[127]

5. CONCLUSION

This article has explored various public health-related flexibilities and their legal status in Tanzania. It has highlighted that the flexibility of public non-commercial use is indeed incorporated within the Patent Act. Under this provision, the law grants the Minister responsible for patent matters the authority to permit a government agency or third party to utilise a patented invention without requiring consent from the patent owner. This flexibility is applicable when a critical public interest, such as public health, is involved. This paper emphasises that this flexibility is effective, as it does not impose many procedural prerequisites for its application. However, it is worth mentioning that this flexibility has not yet been utilised in Tanzania to support public health.

The paper further examined the legal landscape in Tanzania concerning the applicability of the Bolar exception, revealing that this flexibility is not legally recognised. As a result, it cannot be invoked to enhance access to medicines where needed. The lack of this essential flexibility, combined with the non-utilisation of existing options, renders Tanzania's current patent law unresponsive to public health concerns, particularly in facilitating access to medicines. This situation hampers the country's efforts to address the issue of access to essential medications.

Furthermore, the paper demonstrates that the criteria for patentability in Tanzania establish rigorous standards that ultimately hinder the granting of easy patents, resulting in fewer patents. Fewer patents are essential for promoting public health. Regarding the transitional period, the paper has noted that Tanzania has missed a significant opportunity, as it has failed to capitalise on this flexibility. This scenario raises doubts about the effectiveness of the current patent law in supporting public health.

The paper advocates for amending the law to exempt medicines from patent protection while simultaneously establishing a strong patent legal framework that incorporates essential flexibilities outlined in the TRIPS Agreement, which are crucial for promoting public health. In addition to embracing these key flexibilities, the government should fully leverage such options to enhance public health whenever the circumstances permit. By implementing these changes, Tanzanian law could significantly mitigate the impact of IP, particularly patents, on public health.

[126] United Nations Conference on Trade and Development (2011) 'Investment in Pharmaceutical Production in the Least Developed Countries: A Guide for Policymakers and Investment Promotion Agencies' at 40 – 42 available at https://unctad.org/system/files/official-document/diaepcb2011d5_en.pdf [accessed 17 April 2025].

[127] Nirmalya S (2014) 'Transition Period for Trips Implementation for LDCs: Implications for Local Production of Medicines in the East African Community' *Research Paper No. 59* at 6-7 available at https://www.southcentre.int/wp-content/uploads/2014/12/RP59_Transition-Period-for-TRIPS-Implementation-for-LDCs_EN.pdf [accessed 20 January 2025].