THE AfCFTA PROTOCOL ON INTELLECTUAL PROPERTY RIGHTS: A NEW FRAMEWORK FOR ACCESS TO MEDICINES IN AFRICA

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> *Viewing access to medications as a matter of fundamental human rights forces us to face the momentous suffering and loss of life that is occurring in developing countries due to HIV/AIDS, tuberculosis, malaria, and other diseases as not just a tragedy; it forces us to recognise it as a horrific injustice....*[1]
> **Alicia Ely Yamin**

1. Introduction

Access to medicine has been a major public health concern in most developing and least developed countries (LDCs), especially those in Africa.[2] For many decades now, the continent has witnessed the outbreak of several diseases that claimed the lives of millions of people, such as malaria, HIV/AIDS, Ebola and, most recently, Covid-19 and monkeypox. These outbreaks have exposed the medical systems of most African states as weak and inefficient compared to other regions. This is primarily attributable to several factors, including the high cost of medicine, inefficient regulatory frameworks, and the widespread influx of counterfeit drugs in the region. These challenges have sparked extensive debate among academics, experts, and international organisations regarding possible solutions.

Access to medicines in Africa, together with the promotion of broader access to healthcare products and new technologies, has become a matter of great concern for the African Union (AU), its member states and the academic community. Although Africa has made significant progress in healthcare, including the establishment of IP frameworks that promote access, a large segment of its population still lacks access to essential medicines.

This study aims to examine the potential of the AfCFTA Protocol on Intellectual Property Rights (AfCFTA IP Protocol) to alleviate barriers to access to medicines in Africa, notwithstanding the fact that the Protocol has not yet come into force, has not been ratified by any country, and its annexes are still under negotiation. The central question considered in this study is the

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1 AE Yamin 'Not just a tragedy: Access to medications as a right under international law' (2006) 21 *Boston University International Law Journal* 325–370.

2 W Fisher et al 'Fostering production of pharmaceutical products in developing countries' (2021) 43 *Michigan Journal of International Law* 1.

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extent to which the AfCFTA IP Protocol may enhance access to medicines across Africa to address pressing public health concerns.

This research employs a desktop-based approach to discuss, examine, and analyse key issues regarding the topic under review. This approach makes use of both primary and secondary sources and information, including but not limited to the AfCFTA IP Protocol, the TRIPS Agreement and its 2005 amendment, the resolutions of the MC12 Conference, case laws, existing peer review literature and reports from the World Bank, World Trade Organization and the World Health Organization. The objective of the research is to analyse access to medicines, discuss and provide a better understanding about the topic, explore emerging issues, and establish a foundation for future research.

The significance of this study lies in its objective to propose possible solutions in addressing access to medicines in Africa under the newly adopted AfCFTA IP Protocol. This research will add to the existing literature on the subject, which would be of significant benefit to other scholars, governmental agencies and international organisations. If the findings and recommendations are implemented, they could play a pivotal role in developing efficient, reliable, and sustainable mechanisms for enhancing access to medicines across the continent.

1.1 The right to health and access to essential medicines as a legal and human rights obligation

Access to medicines is not only essential for individual well-being, but is also recognised as a fundamental human right in numerous international and regional human rights instruments, as well as in the bills of rights or constitutions of most African states. According to Yamin, human rights decisions influence and affect access to medicines, including the adoption of trade and intellectual property regimes that may affect accessibility.[3] In essence, safeguarding human rights, particularly the right to health, is fundamental to ensuring their full realisation. Access to safe and quality medicines remains a core pillar of the right to health, which has been safeguarded in several human rights documents.

The right to health was first widely recognised in art 25 of the Universal Declaration of Human Rights (UDHR), adopted in 1948 by the United Nations (UN). Although this instrument is not legally binding on UN member states, it has established an important benchmark for subsequent international and regional human rights instruments, and has influenced member states to protect the right to health in their domestic bills of rights and national constitutions. Unlike the UDHR, the International Covenant on Economic, Social and Cultural Rights (ICESCR) imposes a legal obligation on member states to protect the right to health, among others. The ICESCR legally enjoins states to '…recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.[4] This Convention reaffirms the right to

3 AE Yamin 'Not just a tragedy: Access to medications as a right under international law' (2006) 21 *Boston University International Law Journal* 370.

4 ICESCR (1966), art 12.

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health under the UDHR and gives member states the power to adopt measures necessary for the attainment of the right to health, including steps to reduce stillbirth rates and infant mortality, improve environmental and industrial hygiene, and prevent, treat, and control diseases, both epidemic and endemic. It also calls for creating enabling conditions that would assure medical services and attention in the event of sickness.

This Convention has been widely accepted globally, including across Africa, where it has received 51 signatures and 48 ratifications since it was adopted in December 1966.[5] This achievement demonstrates how influential the ICESCR is on the continent and how it forms an integral instrument in the protection of the right to health. It imposes legal obligations on its member states to take responsibility for failing to protect their citizens in this regard.

Similarly, the African Charter on Human and Peoples' Rights (ACHPRs) also imposes legal obligations on its member states to protect the right to health. Article 16(2) of the ACHPRs thus provides that member states are obliged to take necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick. Other international human rights instruments that impose legal obligations on states to protect the right to health include the Elimination of All Forms of Racial Discrimination,[6] the Convention on the Rights of the Child,[7] the Convention on the Rights of Persons with Disabilities,[8] the International Convention on the Elimination of All Forms of Discrimination Against Women,[9] and the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families.[10]

It is evident from the foregoing that governments are not only under a moral duty but also a legal obligation to take all necessary measures to ensure that their citizens have access to essential medicines. Their commitment to improving such access can be assessed through the extent of financial resources allocated annually to the health sector, as well as their consideration of other critical factors, including the pricing of medical products in domestic markets, the enforcement of competition laws, and the regulation of licensing regimes. Furthermore, states have a responsibility to guarantee that medical services and facilities are accessible to all individuals without discrimination based on sex, race, colour, ethnic origin, or any other status.[11]

In *Treatment Action Campaign and Others v. Minister of Health & others* (2002),[12] the Treatment Action Campaign, together with other applicants,

5 UN Human Rights Office of the High Commissioner Status of Ratification Interactive Dashboard on ICESCR, available at: https://indicators.ohchr.org/ (accessed on 14 October 2025).
6 Article 5(e)(iv).
7 Article 24.
8 Article 25.
9 Articles 11(1)(f), 12 and 14(2)(b).
10 Articles 28, 43(e) and 45(c).
11 AE Yamin 'Not just a tragedy: Access to medications as a right under international law' (2006) 21 *Boston University International Law Journal* 327.
12 *Minister of Health & others v Treatment Action Campaign & others* (No 1) (CCT9/02) [2002] ZACC 16; 2002 (5) SA 703; 2002 (10) BCLR 1075 (5 July 2002).

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brought an action against the Government of South Africa, represented by the Minister of Health, for failing to provide the antiretroviral drug nevirapine to pregnant women in order to prevent mother-to-child transmission of HIV. The Constitutional Court of South Africa held that the government had failed to meet the 'minimum core' obligations of the right to health by not ensuring the provision of the antiretroviral drug to the thousands of pregnant women living with HIV/AIDS and therefore had breached its constitutional obligations.

In delivering its judgement, the Constitutional Court relied on the interpretation of the 'minimum core' concept developed by the UN Committee on Economic, Social and Cultural Rights (CESCR) — the body responsible for monitoring state parties' compliance with the International Covenant on Economic, Social and Cultural Rights (ICESCR) — when determining whether a state has violated its legal obligations to uphold the right to health. According to the Committee, 'A State party in which any significant number of individuals is deprived of essential foodstuffs, of essential primary health care, of basic shelter and housing, or of the most basic forms of education is, prima facie, failing to discharge its obligations under the Covenant.'[13]

The Court's decision compelled the South African Government to implement a comprehensive national programme to expand access to antiretroviral treatment. This judgment marked a significant victory for public health and the protection of socio-economic rights in South Africa.

2. The AfCFTA and the Development of IP Regimes in Africa

Africa has long been described by many as the breadbasket of the world, with an unprecedented amount of arable land, natural resources and a youthful population, which makes the continent a potential hub for economic growth. To maintain this status, Africa has established the African Continental Free Trade Area (AfCFTA) — the largest free trade agreement by number of member states globally — to promote meaningful trade in goods and services that will enhance deeper economic and social integration, as well as sustainable development. Since its establishment in 2019, the AfCFTA Agreement has been signed by 54 African states and has received 48 ratifications as of January 2025, with Eritrea being the only state that has neither ratified the agreement nor signed it.[14]

2.1 Brief historical development of IP in Africa

The development of IP in the region dates back to the early 1960s, when one of the earliest regional IP agreements, the African and Malagasy Office of Industrial Property (OAMPI) agreement, which later became the African Intellectual Property Organization (OAPI) in 1977, came into force.[15] The agreement primarily aims to unify IP laws across its seventeen francophone

13 *Minister of Health & others v Treatment Action Campaign & others* (n12) 19.

14 AfCFTA, available at: https://au-afcfta.org/ (accessed on 26 June 2025).

15 OAPI 'OAPI: Historical', available at: http://www.oapi.int/index.php/fr/oapi/presentation/historique (accessed on 17 October 2024).

African member states. Fast forward to 1976: after several failed attempts, the Lusaka Agreement, which established the African Regional Intellectual Property Organization (ARIPO), also came into force to harmonise IP rules across its 22 Anglophone African member states.[16] These two regional bodies have been instrumental in shaping IP administration and laws across Africa since most countries on the continent gained independence, although some of the biggest economies, like Egypt, Nigeria, and South Africa, are not members of either organisation. Notwithstanding, Nigeria and South Africa have been granted observer status by ARIPO. However, only 39 out of the 55 African states are collectively members of OAPI and ARIPO, leaving a significant gap in IP coverage across the continent.

Although both regional bodies are geared towards fostering cooperation among African states in matters relating to IP administration and protection, one major difference between them lies in their substantive and procedural aspects. Unlike ARIPO, OAPI offers a wide range of protection that covers all IP rights, including unfair competition practices, with uniform registration applicable across all its member states. By contrast, ARIPO currently covers only a limited number of IP rights, primarily patents and trademarks, and protection applies only to those member states that have adopted the relevant protocols for those IP rights.

The IP regime in Africa faces multiple challenges, ranging from limited domestic awareness of IP, to inefficient and complex IP registration processes, variations in IP frameworks across African states, and the issue of territoriality, which has deprived many IP owners of enforcing their rights in other jurisdictions.[17] Concerted efforts have been made over the years to create a single IP regime in a bid to address these challenges. In 2016, the AU adopted the Pan-African Intellectual Property Organization (PAIPO) with the aim of establishing a single IP regime in Africa. However, this effort was ultimately unsuccessful due to technical errors in the draft document, which watered down the commitment of member states to ratify it. To date, only seven countries have signed the PAIPO agreement out of the 54 African states. Only Tunisia has ratified the said agreement among the seven signatories.[18]

2.2 Scope and objectives of the AfCFTA IP Protocol

The AfCFTA Agreement and its protocols and annexes cover a wide range of areas, including trade in goods and services, investment, intellectual property rights, dispute settlement, women and youth in trade, digital trade, customs and trade facilitation, and competition policy to accelerate intra-African trade. Meaningful trade under the AfCFTA commenced in 2021 through the Guided

16 ARIPO 'ARIPO: Our History', available at: https://aripo.org/browse/about-us/our-history (accessed on 17 October 2024).

17 L Lundstedt *'Territoriality in Intellectual Property Law'* (PhD Thesis, Stockholm University, 2016) 73–74.

18 Status of the Pan-African Intellectual Property Organization, available at: https://au.int/sites/default/files/treaties/32549-sl-STATUTE_OF_THE_PAN_AFRICAN_INTELLECTUAL_PROPERTY_ORGANIZATION_PAIPO_0.pdf (accessed on 28 May 2025).

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Trade Initiative introduced by the AfCFTA Secretariat. Since then, significant progress has been made, including the introduction of the Pan-African Payment and Settlement System (PAPSS) to ensure an efficient and effective cross-border payment system, the e-tariff book, and mechanisms for addressing the non-tariff barriers (NTBs), among others.

However, one of the most significant achievements in the implementation of the AfCFTA has been the adoption of the AfCFTA IP Protocol in February 2023, which forms the focus of this study. The AfCFTA IP Protocol, among other things, aims to create harmonised rules and principles that promote research and development, technology transfer, and innovation, as well as the protection and enforcement of IP across Africa. It also provides incentives for inventors and IP rights holders. It provides the minimum standards of protection for IP, which contracting member states are obligated to adopt in their national laws. The AfCFTA IP Protocol covers a wide range of IP protection, including but not limited to patents, trademarks, industrial designs, genetic resources, traditional knowledge, copyright and more.

2.3 Unique features of the AfCFTA IP Protocol

The AfCFTA IP Protocol possesses several unique features with the potential to enhance access to medicines in Africa. One of its most notable innovations is the establishment of a regional IP office to accelerate cooperation. This office will help address the challenges posed by the fragmented and multifaceted IP frameworks that have existed since the late 1960s, including the complexity in IP rules and administration. This is a step towards IP unification in Africa. Secondly, for the first time, an IP legal instrument in Africa makes provision for public health emergencies and the local production of pharmaceuticals. Thirdly, unlike existing regional IP regimes, such as ARIPO and OAPI, the AfCFTA IP Protocol is open to all African states for ratification and is not subject to or limited by colonial heritage and/or language barriers, such as Francophone or Anglophone speaking countries.

2.4 Public health provisions under the AfCFTA IP Protocol

Although the annexes to the AfCFTA IP Protocol are yet to be concluded and no African state has ratified the document to date, nonetheless, the AfCFTA IP Protocol has huge potential in transforming the IP landscape in Africa. The AfCFTA IP Protocol has provided for the first time for public health emergencies and local production of pharmaceuticals and the establishment of a regional IP office, which are novel to the IP regime in Africa. Article 21 of the AfCFTA IP Protocol allows member states to take steps deemed necessary to protect public health during emergencies.[19] In doing so, member states can develop appropriate measures consistent with IPRs to foster local production of pharmaceuticals or medicines.[20]

19 AfCFTA Protocol on IPRs, art 21(1).
20 AfCFTA Protocol on IPRs, art 21(2).

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Article 12 of the AfCFTA IP Protocol provides for patent protection. The requirements for granting patent protection over an invention bear a striking similarity to those set out in art 27 of the TRIPS Agreement, which will be discussed later in this article. However, one important thing to note, under art 12, is that member states are encouraged not to adopt laws and policies that will '…hinder access to medicines, vaccines, diagnostics, therapeutics, and other healthcare essential inputs, ingredients and processes and other essential tools consistent with intellectual property treaties to which they are party'.[21] It also enjoins member states to ratify and adopt the provisions of the 2005 Protocol Amending the WTO TRIPS Agreement within three years of the coming into force of the AfCFTA IP Protocol.

3. Patent and Access to Medicines

One of the purposes of IP protection is to promote fair competition in the market and ensure consumer protection. The holder of a patent has exclusive rights recognised by law to prevent or authorise others to make, use, import, sell, or offer for sale the patented products or processes in certain ways.[22] This is subject to certain exceptions, namely when a compulsory licence has been granted by a contracting member state of the TRIPS Agreement and when the patent holder has exhausted their rights over the property, in that the property has been put on the market for sale.[23] Today, most pharmaceutical companies use IP, especially patent protection, to exercise control over their products, thereby limiting third parties from using, producing, and reselling their products. According to Abraham Lincoln, 'the patent system added the fuel of interest to the fire of genius'.[24]

What then constitutes patent protection? There is no generally accepted definition for patents. However, scholars and institutions have proposed many definitions. The WIPO Academy has described patents as '…a legal document that grants an exclusive right on the patented invention, which is a product or process that generally provides a new way of doing something or offers a new technical solution to a problem'.[25] Similarly, Hall defines it as the '…legal rights of an inventor to exclude others from making or using a particular invention'.[26] In other words, a patent is a form of protection granted over products, processes, or technological devices, allowing the patent holder exclusive rights to use, produce, and sell such products for a limited period. The patent holder has the authority to prevent a third party from infringing on the patented product by simply filing for an injunction in court.

21 AfCFTA Protocol on IPRs, art 12(3)(a).
22 World Trade Organisation (WTO) TRIPS Agreement, art 28.
23 TRIPS Agreement, art 6.
24 Abraham Lincoln 'Lincoln: Speeches, patents and slavery', available at: https://belda.blog/2020/07/16/lincoln-speeches-patents-and-slavery/ (accessed on 26 July 2025).
25 WIPO Academy 'General course on intellectual property - Module 7: Patent' (2019) at 6.
26 BH Hall 'Patents and patent policy' (2007) 23(4) *Oxford Review of Economic Policy Oxford Review of Economic Policy* 568–587, available at: https://www.researchgate.net/publication/24008480_Patents_and_Patent_Policy/citations (accessed on 25 July 2025).

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However, for a product to be granted patent protection, it must meet the requirements set out in art 27 of the TRIPS Agreement. Article 27 allows contracting member states to grant patents for '…any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application'.[27] For patent protection to be granted for any invention, it must meet both the substantive requirements — set out in art 27 — and the procedural requirements — set out by the IP administration office of each member state. The invention for which patent protection is sought must be new to the existing body of knowledge. What constitutes an invention — newness, inventive steps, and usefulness in a particular industry — is determined by the contracting member states, which can develop policies in that regard, as long as the policies do not contravene the TRIPS Agreement. Although novelty and inventive steps under this article are not defined by the TRIPS Agreement, contracting member states may assign their own meanings to these terms; however, for 'inventive steps', it must be synonymous with 'non-obviousness'.

Furthermore, contracting member states have the flexibility under the TRIPS Agreement to exclude patent protection in certain circumstances, such as to ensure '*ordre public*' or morality, and to '…protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law'.[28] Furthermore, states can also exclude patent protection for technologies invented for the purpose of conducting diagnostic, therapeutic and surgical methods for the treatment of humans or animals. The same rule applies to 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes'.[29]

3.1 Flexibilities under the TRIPS Agreement

3.1.1 *Compulsory licenses*

Compulsory licenses are the most utilised flexibility provided under the TRIPS Agreement. These are licenses issued or granted by a member state or a judge of a competent court from that state, permitting the government or a third party to utilise the subject matter of a patent without the authorisation of the patent holder.[30] These licenses are usually granted for the greater public good or to meet the needs of an emergency that ought to be addressed using such patent. Upon granting such a license, the grantee has the right to manufacture and use generic products of the patent.[31] This is the case in most public health emergencies or pandemic outbreaks.

27 TRIPS Agreement, art 27(1).
28 TRIPS Agreement, art 27(2).
29 TRIPS Agreement, art 27(3).
30 MSF Briefing Document 'Compulsory licenses the TRIPS waiver and access to Covid-19 medical technologies' (2021) 2.
31 Ibid.

https://doi.org/10.47348/SAIPL/v13/i2a10

Articles 8 and 31 of the TRIPS Agreement reaffirm the right of member states in granting compulsory licenses. Article 8(1) provides that member states have the right to adopt legislation that protects public health and promotes public interest, provided such laws are consistent with the TRIPS Agreement provisions. These measures must be necessary for the prevention of abuse of IP by right holders or practices that unreasonably restrain trade or prejudicially affect the transfer of technology.[32] On the other hand, art 31 provides the condition precedent necessary for granting compulsory licenses. Among other things, a member state granting compulsory licenses must consider the following: first, the state proposing to grant the licence must have initiated dialogue to seek authorisation from the patent holder on reasonable commercial terms, but such dialogue has not produced the desired outcomes or been successful within a reasonable time.[33] However, a member state can waive the need for such authorisation in situations of urgency and emergency.[34] Second, the compulsory licence must be utilised only for the purpose for which it was granted and must not be assigned to another third party.[35]

Third, the end product of the compulsory licence must be used predominantly in the domestic market of the state that granted it.[36] This final condition has been a major setback in the granting compulsory licenses over the years, as most LDCs in Africa lack the capacity to utilise the compulsory licence to supply their domestic market.[37]

To have a better understanding of compulsory licenses, the provisions of arts 8 and 31 must be read in tandem with arts 27, 30 and 44.

3.1.2 *Parallel importation (TRIPS Agreement art 6)*

Parallel importation is one of the most utilised flexibilities of the TRIPS Agreement. This practice involves importing goods into a state without seeking the authorisation of the patent holder or their licensee.[38] The importer purchases the product from a third party outside their own country, rather than importing it from the manufacturer, patent holder, or their lawful licensee.[39] The technique is a legitimate practice allowed under the 'doctrine of exhaustion' established in art 6 of the TRIPS Agreement and a common practice in international intellectual property (IP) protection. The practice not only creates economic advantages for developing countries but also helps

32 TRIPS Agreement, art 8(2).
33 TRIPS Agreement, art 31(b).
34 WTO 'Compulsory licensing of pharmaceuticals and TRIPS', available at: https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (accessed on 29 October 2025).
35 TRIPS Agreement, art 31(c).
36 TRIPS Agreement, art 31(f).
37 MA Desai & E Lilly 'Compulsory licensing: Procedural requirements under the TRIPS agreement' (2016) 18 *Pharmaceuticals Policy and Law* 35, available at: https://www.ifpma.org/wp-content/uploads/2023/01/i2023_4.-Compulsory-Licensing-Procedural-Requirements-under-the-TRIPS-Agreement.pdf (accessed on 29 October 2025).
38 L Mugambe *'The exceptions to patent rights under the WTO-TRIPS Agreement: Where is the right to health guaranteed?'* (2002) (LLM Dissertation, University of Western Cape) 29.
39 Ibid.

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to promote competition.[40] The 'doctrine of exhaustion' holds that the patent holder's exclusive rights over the property diminish immediately upon the first sale of the product. Consequently, patent holders or their lawful licensees have no right to prevent third parties from commercially exploiting the product.[41] The rationale behind this doctrine is that the patent holder receives their reward the moment the product is put on the market or the first sale is made; as a result, third parties enjoy the right to import such products for commercial purposes without the patent holder's knowledge or consent.

For the purposes of this study, parallel importation refers specifically to the purchasing of pharmaceutical products from a third party outside the importer's home country without seeking the consent of the patent holder, their licensee, or the manufacturers of the products. This is a common practice among many contracting parties of the TRIPS Agreement, given that pharmaceutical companies often sell their products at lower prices in one country than in others. South Africa and Kenya are typical examples of African countries that have actively engaged in parallel importation of HIV/AIDS and other medical products over the years. In Kenya, the Industrial Property Act of 2001 allows for parallel importation to improve access to medicines. These two countries have a high rate of HIV/AIDS patients, which makes the development of such frameworks necessary.

The exhaustion of patent rights varies from one jurisdiction to another. Some countries practise 'international exhaustion' of rights, whereby the patent is exhausted upon the first sale in the international market; others practise 'national exhaustion' of rights, which allows patent holders to prevent parallel importation by third parties because the patent right is only exhausted after the first sale is made in the patent holder's domestic market. The third form of exhaustion of right is 'regional exhaustion', which takes place immediately after the first sale is made within the region of the patent holder.[42]

Importers may face both legal and regulatory challenges depending on the applicable exhaustion of rights doctrine practised by the country of importation. This varies from country to country. Importers may have to navigate through complex legal frameworks in order to successfully utilise the provision.[43] On the other hand, parallel importations are detrimental to the patent holder, as the importer is not obligated to enter into a licence agreement with the patent holder.[44]

40 Mugambe (n38) 31.

41 TE Dyah A, LM Hayyanul Haq & A Atsar 'The parallel imports of invention patents in pharmaceutical products' (2022) 10(7) *International Journal of Scientific Research and Management (IJSRM)* 360.

42 DR Agarwal 'International exhaustion of patent rights and parallel imports: A comparative study between India and Japan' (2017) iv, available at: https://www.iip.or.jp/e/summary/pdf/detail2016/e28_06.pdf (accessed on 25 October 2025)

43 B Brewer 'Parallel imports, a global phenomenon, and a very grey area regarding international trade' (2024) *Braumiller Law Group*, available at: https://www.braumillerlaw.com/parallel-import-are-global-phenomenon-and-a-grey-area/ (accessed on 15 October 2025).

44 TE Dyah A (n41) 360.

Parallel importation is not explicitly covered under the TRIPS Agreement, nor is it defined in the TRIPS Agreement.[45] However, it is indirectly provided for under art 6 of the TRIPS Agreement, which forms the legal basis for parallel importation of patented products. Article 6 establishes the doctrine of exhaustion and provides that 'for the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights'. This simply means member states are allowed to establish their own regime on exhaustion of right without challenge, provided that the principles of national treatment and most favoured-nation (MFN) treatment under arts 3 and 4 of the TRIPS Agreement are complied with.[46] These provisions may also be read alongside art 7 of the TRIPS Agreement, which encourages member states to create a conducive IP framework.

3.1.3 *Bolar or early working exception*

The Bolar or early working exception is another flexibility of the TRIPS Agreement. Like parallel importation, the Bolar or early working exception is not explicitly provided for under the TRIPS Agreement, nor is it defined. Notwithstanding, the Bolar or early working exception is largely accepted under art 30 of the TRIPS Agreement, which states that member states

> … may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[47]

Under this exception, potential competitors are allowed to utilise patented inventions devoid of the patent holder's authorisation. Given that, the competitor's right to use the patented invention or product is limited only for the purpose of conducting research or in order to obtain regulatory approval or registration of a generic product before the patent holder's right over the product expires.[48] Hence, the use of the patented product must not be for commercial purposes; otherwise, the user would be held liable for infringing the patent.[49] The underlying reason or rationale for allowing this flexibility is to foster research and education, thereby allowing competitors or researchers to study and develop existing patents for future purposes.

45 DR Agarwal 'International exhaustion of patent rights and parallel imports: A comparative study between India and Japan' (2017) ii, available at: https://www.iip.or.jp/e/summary/pdf/detail2016/e28_06.pdf (accessed on 25 October 2025).

46 See para 5(d) of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, WT/MIN(01)/DEC/2 available at: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (accessed on 25 October 2025).

47 TRIPS Agreement, art 30.

48 A Tridico et al 'Facilitating generic drug manufacturing: Bolar exemptions worldwide' (2014), available at: https://www.wipo.int/en/web/wipo-magazine/articles/facilitating-generic-drug-manufacturing-bolar-exemptions-worldwide-38860 (accessed on 25 October 2025).

49 D Doubinsky 'Application of the Bolar exception: Different approaches in the EU (2025) 15, available at: https://www.econstor.eu/bitstream/10419/312867/1/1915185580.pdf (accessed on 25 October 2025).

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In the case of *Roche Products, Inc. v. Bolar Pharmaceutical Co*.,[50] which established this exception, Roche brought an action against the defendant for using their patented drug for clinical trials. At first instance, the court held in favour of Bolar, stating that the mere use of a product for the purpose of obtaining regulatory approval does not amount to an infringement. However, this decision was overturned on appeal. The appellate court held that Bolar's action amounted to an infringement because they were using the trials for 'commercial purposes'. In delivering judgment, Judge NICHOLS held that:

> Bolar's intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the '053 patent. Bolar may intend to perform "experiments," but unlicensed experiments conducted with a view to the adaption of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention…It is no dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry," when that inquiry has definite, cognizable, and not insubstantial commercial purposes.[51]

4. The Protocol Amending the TRIPS Agreement 2005 and Access to Medicines

The Protocol amending the TRIPS Agreement in 2005 is a game-changer in IP regulation and global public health. The Protocol, which was adopted in December 2005, came into force in January 2017 and overturned the 2003 TRIPS Agreement waiver, a temporary policy waiver that allows exporting countries to produce generic versions of patented products under compulsory licences and export them to other importing countries.[52] To date, 100 WTO member states have ratified the protocol, including 31 African states.[53] The Protocol is open for ratification until December 2025.[54]

The Protocol aims to increase access to medicines through patent flexibility. It removes limitations imposed on granting compulsory licences under art 31 of the TRIPS Agreement, especially paragraph (f), which requires that products manufactured under compulsory licences be predominantly used for the domestic market of the state that grants them. This provision was a significant setback for importing countries — LDCs — particularly those in Africa, which could not utilise compulsory licences due to a lack of both technical and financial capacity. However, the new provision under the Amendment Protocol now allows exporting countries to grant compulsory licences for pharmaceutical products and to export them to importing countries to meet their needs. This presents an opportunity that African states should

50 *Roche Products Inc. v. Bolar Pharmaceutical Co.,* 733 F.2d 858 (Fed. Cir. 04/23/1984), available at: https://biotech.law.lsu.edu/cases/IP/patent/roche_v_bolar.htm (accessed on 25 October 2025).

51 Supra.

52 World Trade Organization 'Amendment of the TRIPS Agreement', available at: https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed on 23 July 2025).

53 AfCFTA (n14).

54 AfCFTA (n14).

take advantage of, given their historical lack of capacity to utilise compulsory licences. Rwanda was the first importing African country to notify the WTO in 2008 of its intention to utilise this provision by using Canada to procure TriAvir drugs for the treatment of HIV/AIDS.[55]

4.1 The implementation of the TRIPS Agreement and its Amendment Protocol 2005

The implementation of the TRIPS Agreement in Africa has been challenging due to several factors, including the significant deficit of IP experts in the region, fragmented IP frameworks, and a lack of alignment with African best interests. Thus, Deere pointed out that the TRIPS Agreement is nothing more than 'a victory for those multinational companies determined to raise international IP standards and boost IP protection in developing countries'.[56] In other words, multinational companies from developed states have used the TRIPS Agreement as a tool to protect their products in LDCs and developing countries. Similarly, Prof. Ncube also noted that the implementation of the Agreement could be problematic, given that it was not concluded in the best interest of LDCs — of which Africa is no exception — since some of the minimum standards set out in the agreement are not applicable to them.[57]

Notwithstanding the above-mentioned challenges, there are prospects of transforming the IP regime in Africa, especially in the promotion of public health. The Protocol amending the TRIPS Agreement of 2005 has removed some limitations imposed by the TRIPS Agreement on granting compulsory licences over the years. This Protocol amends art 31(f) and allows exporting countries to now grant compulsory licences and manufacture pharmaceuticals, then export them to importing countries.

4.2 Assessment of IP, economic, and infrastructural constraints limiting access to medicines in Africa

4.2.1 *Restrictive IP regulations*

Africa faces tremendous challenges in accessing medicines and pharmaceutical products, especially during public health emergencies. One of the factors that has stifled access to medicines is the enforcement of stricter patent laws. According to Joseph Stiglitz, a prominent economist who won the Nobel Prize in 2001, and Jagdish Bhagwati, 'patent protectionism' is unfair, inefficient, and inconsistent with the free trade agenda.[58] Given that once a patent is granted for a pharmaceutical product, the patent holder automatically has exclusive

55 M Nkomo 'Rwanda's new intellectual property law and compulsory licensing for export under the WTO: Not quite a panacea' (2013) 21(2) *African Journal of International and Comparative Law*, available at: https://euppublishing.com/doi/10.3366/ajicl.2013.0062 (accessed on 25 July 2025).

56 C Deere 'The implementation game: The TRIPS Agreement and the global politics of intellectual property reform in developing countries' (2009) *Oxford University Press* 1.

57 CB Ncube 'Intellectual property policy, law and administration in Africa: Exploring continental and sub-regional cooperation' (2016) at 14.

58 M Weisbrot 'Rich country protectionism puts WTO on the slow track' (2001), available at: https://twn.my/title/twr268j.htm (accessed on 25 October 2025).

rights to use, sell, and produce those products, as well as prevent third parties from doing so. Patent law protects most essential drugs manufactured by larger pharmaceutical companies, primarily in developed countries, and this prevents smaller pharmaceutical companies from utilising such patents without the consent of the patent holder when the need arises.

4.2.2 *Limited capacity to meet the continent's need for medicines*

Africa has a population of about 1.4 billion people, and no single pharmaceutical company, within or outside the continent, could feasibly meet the growing demand for medicines. The continent has approximately 600 local pharmaceutical companies serving its vast population, around 80% of which are located in eight countries: Algeria, Egypt, Morocco, Nigeria, Tunisia, Ghana, Kenya, and South Africa.[59] Among these, only a few pharmaceutical companies focus on the manufacturing of Active Pharmaceutical Ingredients (APIs), while the majority concentrate on formulation manufacturing or the production of generic products.[60] According to the African Union, as of 2022, the continent had the capacity to manufacture only about 1% of the vaccines required to meet its total demand.[61] As such, it is evident that no single pharmaceutical company has the capacity to meet the medical demand in Africa, given the continent's growing population.

4.2.3 *Wide spread of poverty*

Poverty is another major factor hampering access to medicines. Africa is home to the largest number of LDCs in the world. Most people live in abject poverty. According to studies, over 558.8 million of the population in Sub-Saharan Africa find it difficult to even afford one meal a day and live on less than US$2.15 per day.[62] In the World Bank report on the Global Poverty Update, the level of poverty in Sub-Saharan Africa has increased from 37% to 45.5% in 2022.[63] As a result, the majority of people are unable to afford medicines when they become ill, a situation made worse by the high prices charged by pharmaceutical companies. Ironically, Africa is rich in genetic resources, and some of the genetic resources used by multinational pharmaceutical companies to produce their medicines are sourced from Africa.

59 K Narsai & D Abudu 'African pharmaceutical sector landscape analysis: Focus on pharmaceutical manufacturing and trade under the AfCFTA' (2024).

60 Ibid.

61 Africa Centre for Diseases Control and Prevention 'Partnerships for African Vaccine Manufacturing (PAVM) framework for action' (2022) 28.

62 JH Lønborg, M Viveros RA Castaneda Aguilar, C Lakner, GL Ibarra, MC Nguyen & SK Tetteh Baah 'June 2025 Global Poverty Update from the World Bank: 2021 PPPs and New Country-Data' (2025), available at: https://blogs.worldbank.org/en/opendata/june-2025-global-poverty-update-from-the-world-bank--2021-ppps-a (accessed on 16 July 2025).

63 Ibid.

4.2.4 *Lack of proper infrastructure*

In addition, Africa lacks the necessary infrastructural development to create an enabling environment for access to medicines. Factors such as technology transfers, reliable transport networks, electricity, and other essential services are needed to address the access challenges the continent faces. Transporting medical products within and into the continent for distribution adds extra costs to the market price of the product due to poor road networks. The costs of medical products will decrease if the drugs are manufactured on the continent, as local production would reduce transportation expenses, create jobs, and support skills and technology transfer.

4.2.5 *The high influx of falsified and counterfeit drugs*

Another significant challenge affecting access to medicine is the high influx of falsified and substandard drugs. According to the United Nations Office on Drugs and Crime (UNODC), approximately half a million people die annually in Sub-Saharan Africa as a result of consuming falsified and substandard medicines, and the continent loses around US$3.5 billion each year through the purchase of these medicines.[64] The issue of substandard and falsified medicines is critical to improving access to medicines; if left unaddressed, it will undermine the efforts to improve access to medicines. The high influx of falsified and substandard medicines also defeats one of the purposes of IP protection, which is to create incentives for inventors or patent holders. The continent will continue to incur losses if this challenge is not addressed, and it will discourage inventors or patent holders from investing in Africa.[65] These medical products are very harmful to consumers' health, as they have zero or minimal effect,[66] and, in some cases, when mixed with safe and effective drugs, can contribute to 'drug-resistant strains' of the diseases they are intended to cure.[67]

5. Policy Recommendations for Reform, Regional Cooperation, and Sustainable Healthcare Innovation

Having considered the challenges mentioned above, the following strategies are recommended as possible solutions to alleviate access to medicines in Africa. Although the AfCFTA IP Protocol is yet to take effect, there remains huge potential for it to enhance access to essential medicines and promote public health on the continent. One of the strategies to alleviate access to

64 BA Mekonnen, MG Yizengaw & MC Worku 'Prevalence of substandard, falsified, unlicensed and unregistered medicine and its associated factors in Africa: A systematic review' (2024) 17(1) *J Pharm Policy Pract.* 2375267, available at: doi:10.1080/20523211.2024.2375267(accessed on 29 October 2025); see also United Nations Office on Drugs and Crime (UNODC), available at: https://news.un.org/en/story/2023/02/1133062 (accessed on 29 October 2025).

65 W Fisher et al 'Fostering production of pharmaceutical products in developing countries' (2021) 43 *Michigan Journal of International Law* 7.

66 Fisher (n65) 8.

67 Fisher (n65) 8.

medicines in Africa is to utilise the provisions set out in the TRIPS Agreement, particularly the Amendment Protocol of 2005. This raises the question: How can the Protocol amending the TRIPS Agreement alleviate barriers to access to medicines? Following the challenges encountered in implementing the TRIPS Agreement, particularly in granting compulsory licences to address public health concerns, the Protocol amending the TRIPS Agreement 2005 was adopted. This Protocol specifically amends art 31 of the TRIPS Agreement, which deals with the granting of compulsory licences by states to third parties. Through the relaxation of patent protection under the Protocol amending the TRIPS Agreement, African countries can effectively grant compulsory licences. In essence, member states are obliged to ratify this Protocol and adopt its provisions in their domestic IP policy.

Another strategy is the establishment of a regional multilateral pharmaceutical company or agency responsible for utilising compulsory licences, especially where the states that grant the licences lack the capacity to manufacture such medicines. As noted earlier, most African states lack the technical and financial capacity to establish domestic pharmaceutical companies, making it difficult for them to utilise or grant compulsory licences. This multilateral pharmaceutical company will step in whenever a member state is in dire need of an essential drug supply. In doing so, countries could rely heavily on the Pandemic Treaty recently adopted by the WHO. This treaty provides a legal framework allowing regional bodies to take certain steps to alleviate access to medicines and tackle public health emergencies. Article 10 of the treaty provides that:

> The Parties shall take measures, as appropriate, to achieve more equitable geographical distribution and rapid scale-up of the global production of pandemic-related health products and increase sustainable, timely, and equitable access to such products, as well as reduce the potential gap between supply and demand during pandemic emergencies…[68]

Furthermore, African countries should also consider the ratification and strict adoption of the provisions of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation. As the title of the Protocol rightly states, the Protocol aims to ensure a fair and equitable share of benefits from genetic resources. As stated above, Africa is home to more than 45,000 genetic resources, many of which are used in the production of pharmaceutical products and medicines.[69] In view of this, African states should take advantage of the Nagoya Protocol and ensure its strict implementation in their domestic IP policies. A fair and equitable share of benefits could be in the form of financial returns, which could improve the economic lives of Africans, or in kind, providing end products to communities at a lower cost.

Moreover, member states should consider utilising parallel imports as an alternative to granting compulsory licences, since the substantial cost of

68 WHO Pandemic Agreement 2025, art 10.

69 KC Nnadozie et al 'Plant genetic resources in Africa's renewal' IELRC Working Paper 2002–3, available at: https://www.ielrc.org/content/w0203.pdf (viewed on 26 July 2025).

establishing pharmaceutical companies at the domestic level. Many African countries do not have a single pharmaceutical company, whether privately or publicly owned. Accordingly, importing essential medical products or medicines from other states that produce affordable generic drugs is a practical option. Countries such as China and India have large pharmaceutical industries that manufacture the generic versions of essential medical products, which African states may purchase. These medicines are sold at affordable prices, and given the scale of production in both countries, their mass production will help meet the rising need for medicines in Africa.

6. Conclusion

In conclusion, access to medicines is not a problem unique to Africa; it is a global one. The problem remains a major public health and human rights concern in Africa, where weak healthcare systems, restrictive IP frameworks, limited domestic manufacturing capacity, and economic inequality continue to hinder equitable access to essential medicines. Despite the protection of the right to health under international and regional human rights instruments such as the UDHR, the ICESCR, and the African Charter on Human and Peoples' Rights, many African states still grapple to fulfil both their moral and legal obligations to guarantee this right. The prevalent health crises experienced across the continent demonstrate that access to safe, effective, and affordable medicines remains central to achieving broader public health goals and sustainable development.

The adoption of the AfCFTA IP Protocol marks a significant milestone in Africa's pursuit of a harmonised and development-oriented IP regime. Although the AfCFTA IP Protocol has not yet come into force, its provisions — particularly those relating to public health emergencies, compulsory licensing, and the establishment of a regional IP office — indicate strong potential for advancing local pharmaceutical production and promoting access to medicines. Incorporated alongside the flexibilities allowed under the TRIPS Agreement and its 2005 Amendment Protocol, the AfCFTA framework could enable African states to strike a balance between protecting IP rights and safeguarding public health. The success of this framework, however, will depend largely on coordinated implementation, robust institutional capacity, and member states' willingness to integrate these provisions into their domestic legal systems.

Nevertheless, the realisation of equitable access to medicines in Africa cannot rely solely on legal instruments or trade policies. It requires a multidimensional approach that strengthens healthcare infrastructure, supports research and innovation, combats the proliferation of counterfeit medicines, and prioritises the fair distribution of medical resources. The establishment of regional pharmaceutical production hubs, the adoption of benefit-sharing frameworks under the Nagoya Protocol, and the use of innovative procurement models are practical measures that could reinforce the continent's self-sufficiency in medicine production and distribution. A coordinated continental strategy under the AfCFTA could also help

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African countries save money, get ready for future pandemics, and make sure that public health is ready for them.

In summary, the advancement of access to medicines in Africa lies at the intersection of public health, trade, and human rights. The AfCFTA IP Protocol provides an unprecedented opportunity to reshape the continent's IP landscape toward a health-centred development agenda. However, its transformative impact will depend on effective domestic implementation, sustained political commitment, and inclusive governance that prioritises human well-being over commercial interests. If duly executed, the AfCFTA could become not only a catalyst for economic integration but also a cornerstone for realising the right to health and ensuring that no African is denied life-saving medicines due to poverty, geography, or inequitable global trade practices.

https://doi.org/10.47348/SAIPL/v13/i2a10