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## **Intellectual Property Rights and Public Health: A Critical Examination of the AfCFTA Framework**

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# Intellectual Property Rights and Public Health: A Critical Examination of the AfCFTA Framework

Chimdessa Fekadu Tsega

**Abstract—Background:** The African Continental Free Trade Area Intellectual Property Rights Protocol (AfCFTA IP Protocol) incorporates several public health-related provisions designed to enhance health across the free trade area. This paper evaluates these provisions and assesses their potential to advance health outcomes within the region.

**Methods:** The paper employs a black letter methodology, analysing the substance of the provisions within the AfCFTA IP Protocol. Additionally, it makes comparative assessments with similar treaties to highlight strengths and weaknesses in the context of public health.

**Results:** While the Protocol includes important provisions on public health, it lacks substantive obligations and effective enforcement mechanisms. Furthermore, the Protocol does not address significant recent developments in the international regime that could have been utilised to strengthen public health initiatives across the region.

**Conclusions:** This paper shows that the AfCFTA IP Protocol upholds existing international regulations concerning IP and public health, while lacking proactive substantive elements. While this allows AfCFTA members to use IP for health-related issues, the absence of detailed provisions limits the potential to effectively address public health challenges across the continent. This shortfall represents a missed opportunity to leverage IP for improved health outcomes in the region.

**Index Terms—** Africa; Health Services Accessibility; Intellectual Property; Patents as Topic; Public Health.

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## I. INTRODUCTION

The COVID-19 pandemic has delivered stark lessons to Africa's healthcare ecosystem, exposing critical vulnerabilities that demand urgent attention. The lack of adequate therapeutics, the severe shortage of medical supplies such as masks and ventilators, and delayed access to vaccines, especially at the early stages of vaccine production, have underscored the pressing need for local capability-building and self-reliance to combat future health emergencies. While the pandemic brought these challenges to the forefront, it is important to recognise that the underlying problems have long plagued the continent's healthcare system.

Established against this backdrop, the African Continental Free Trade Area (AfCFTA) represents the latest and most comprehensive endeavour towards achieving continental integration. Initially proposed by the African Union (AU) in January 2012, the AfCFTA aims to establish a liberalised market for goods and services by reducing and eliminating tariff and non-tariff barriers across the entire region.<sup>1</sup> The AfCFTA Agreement officially came into effect on May 30, 2019, with trading under its provisions commencing on January 1, 2021, effectively establishing a single market with free movement of goods, people, and investment.<sup>2</sup>

One area which the AfCFTA is expected to transform is the intellectual property (IP) sector. Recognising the significance of IP for trade and development, the AfCFTA explicitly includes cooperation on intellectual property as one of its specific objectives under Article 4 of the AfCFTA Agreement.<sup>3</sup> In February 2023, the AU Assembly of Heads of State and Government adopted the AfCFTA Protocol on the Protection of Intellectual Property Rights (AfCFTA IP Protocol).<sup>4</sup> This Protocol is designed to provide a coherent and unified legal framework for the protection of IP across the continent, thereby enhancing legal certainty for creators, innovators, and investors. It also aims to facilitate the

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<sup>1</sup> United Nations Economic Commission for Africa, *Governing the African Continental Free Trade Area-Regional Economic Communities Interface*, (Addis Ababa, 2021) 1-3.

<sup>2</sup> African Union. *Agreement Establishing the African Continental Free Trade Area (AfCFTA Agreement)*. 30 May 2019.

<sup>3</sup> *Ibid*, Article 4(c).

<sup>4</sup> African Union. *Protocol to the Agreement Establishing the African Continental Free Trade Area on Intellectual Property Rights (Draft)*. 19 February 2023.

exchange of best practices and foster cooperation among national IP offices.

The AfCFTA Agreement, under Article 8, provides that, upon adoption, the Protocol shall form an integral part of the agreement. While some observers draw parallels with Article II (2) of the Marrakesh Agreement, suggesting the concept of a single undertaking, it is essential to clarify that the Protocol does not automatically bind all AfCFTA Agreement signatories upon adoption by the AU Assembly.<sup>5</sup> It should be noted that the term ‘upon adoption’ in Article 8 explicitly refers to the adoption of the Protocol individually by State Parties, not solely by the AU Assembly. Furthermore, the Protocol is slated to enter into force 30 days after the deposit of the 22nd instrument of ratification.<sup>6</sup>

IP and public health are intricately linked, as IP rights can significantly influence access to essential medicines and healthcare innovations. While robust IP protections are intended to incentivise research and development, they can also create barriers to affordability and availability of life-saving treatments, particularly in low- and middle-income countries. The tension between safeguarding inventors’ rights and ensuring public access to healthcare resources is a critical issue; thus, frameworks like the AfCFTA IP Protocol must strive to balance these interests. This paper examines the Protocol’s approach to public health by examining its main public health-related provision. As the intersection between IP and public health has become a point of contention, the paper views the Protocol in light of its international counterparts, specifically the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement).

## II. METHOD

The paper primarily employs a black letter methodology, focusing on analysing the content of public health-related provisions in relation to the international legal framework. It also conducts, where necessary, a cross-sectional analysis with other relevant treaties addressing IP and public health. This black letter analysis offers a precise assessment of the law’s substance and its shortcomings, enabling

the formulation of accurate conclusions and relevant recommendations. By comparing various legal texts, the study aims to highlight gaps and suggest improvements.

## III. RESULTS

### *Compulsory Licensing and the TRIPS Amendment*

Although the Protocol does not explicitly establish a standalone compulsory licensing exception, it is inherent in the clause outlined in Article 12(2), which recognises the right of State Parties to introduce exceptions consistent with international IP treaties. Furthermore, the protocol mandates State Parties to ensure that their patent legislation does not hinder access to medicines, vaccines, diagnostics, therapeutics, and other essential healthcare inputs, ingredients, processes, or essential tools, consistent with international IP treaties.<sup>7</sup>

The Protocol specifically addresses compulsory licensing concerning pharmaceutical products, aligning with the principles of the Doha Declaration and the Article 31bis amendment to the TRIPS Agreement. This is articulated in Article 12(3)(b), which requires State Parties that are WTO members to ratify the Article 31bis amendment within three years from the protocol’s coming into force. Non-WTO member State Parties are required to establish procedures under Article 31bis within three years from the protocol’s coming into force.<sup>8</sup> The explicit reference to Article 31bis is pivotal, as it outlines a procedure for countries with insufficient or no manufacturing capacity to import pharmaceutical products through the mechanism of compulsory licensing.<sup>9</sup> The mandate for non-WTO member State Parties to establish procedures under Article 31bis underscores the paramount importance placed by the Protocol’s framers on addressing access to affordable medicine.

However, the Protocol does not specify the conditions for compulsory licensing. State Parties are given complete autonomy to determine the grounds and conditions for issuing compulsory licenses within their domestic legislation. Some countries have effectively utilised this mechanism to secure

<sup>5</sup> See for example, Regis Tann Simo, ‘Non-Exclusivity and an Ocean of Possibilities: The AfCFTA Jurisdictional Lex Specialis’ (2023) 20(2) *Transnational Dispute Management* 2.

<sup>6</sup> AfCFTA Draft IP Protocol, Article 34.

<sup>7</sup> AfCFTA Draft IP Protocol, Article 12(3)(a).

<sup>8</sup> AfCFTA Draft IP Protocol, Article 12(3)(c).

<sup>9</sup> Anna S.Y. Wong, Clarke B. Cole & Jillian C. Kohler, ‘TRIPS Flexibilities and Access to Medicines: An Evaluation of Barriers to Employing Compulsory Licenses for Patented Pharmaceuticals at the WTO’ (2022) 168 *South Centre Research Paper* 28.

drugs at reduced costs.<sup>10</sup> While the TRIPS Agreement permits compulsory licensing, its utilisation must comply with TRIPS provisions and the international obligations of WTO members. Article 31 of the TRIPS Agreement outlines various conditions for the lawful use of compulsory licensing, including a requirement to make efforts to obtain a voluntary license on reasonable terms within a reasonable period of time.<sup>11</sup> Compulsory licenses can only be issued after unsuccessful attempts to secure a voluntary license. This requirement can be waived by member states in case of national emergency, other circumstances of extreme urgency, or public non-commercial use.<sup>12</sup>

The Protocol, in addressing public health emergencies, does not impose specific limitations or exceptions, granting State Parties the authority to take any action they deem necessary to address essential public health interests. As clarified in the Doha Declaration, states have the freedom to determine the grounds and procedures for issuing compulsory licenses.<sup>13</sup> However, while exercising this authority, they must ensure compliance with international obligations, as articulated in Article 21(1) of the Protocol.

Compulsory licensing, as a crucial mechanism for governments in matters related to public interest, local non-working of patents, and combating anti-competitive practices, is particularly vital for countries with insufficient or no local manufacturing capacity. The TRIPS amendment, Article 31bis, establishes a procedure for these countries to import patented pharmaceutical products under compulsory licensing, subject to the specified conditions. While the Protocol mandates State Parties to incorporate the Article 31bis amendment into their national legal frameworks irrespective of their WTO membership status, a notable deficiency lies in the absence of comprehensive provisions regarding the

grounds and procedures for compulsory licensing. It is observed that procedural requirements render impractical the implementation of Article 31bis by a resource-poor importing country to address emergency situations.<sup>14</sup> This challenge can be addressed through regional agreements, such as the AfCFTA IP Protocol. Article 31bis(3) of the TRIPS Agreement, under certain conditions, permanently waives Article 31(f) for a member of a regional trade agreement (RTA) producing a pharmaceutical product for other members of the same RTA. It provides that “the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the RTA that share the health problem in question.”<sup>15</sup>

The invocation of Article 31bis(3) is contingent upon three conditions: (i) the countries involved must be members of a recognised free trade agreement (FTA), (ii) at least half of the FTA members must be least developed countries (LDCs), and (iii) the FTA member seeking compulsory licensing must be the importing country but is allowed to distribute the pharmaceutical product to other FTA members facing the same health problem.<sup>16</sup> The AfCFTA IP Protocol qualifies for this exception as more than half of its members fall under the category of LDC. Thus, it is prudent for the Protocol to capitalise on this exception so that State Parties may effectively navigate the complexities of compulsory licensing in a manner that aligns with the conditions of Article 31bis(3). Under Article 21(3), the Protocol provides that “State Parties shall ensure regional cooperation to provide for greater economies of scale and to develop regional value chains critical for the competitiveness and sustain-

<sup>10</sup> For instance, studies indicate that Thailand has successfully used compulsory licensing to reduce the cost of drugs for cancer, HIV/AIDS, and coronary diseases by 98 percent using compulsory licenses issued between 2006 and 2008. See Martin Khor, ‘*Patents, Compulsory Licenses and Access to Medicines: Some Recent Experiences*’, Third World Network, 11.

<sup>11</sup> World Trade Organization. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), 15 April 1994, Article 31.

<sup>12</sup> TRIPS Agreement, Article 31(b).

<sup>13</sup> World Trade Organization. Declaration on the TRIPS Agreement and Public Health (Doha Declaration), WT/MIN(01)/DEC/2. 2001 Nov 20. Paragraph 5. See also Duncan Matthews, ‘WTO Decision on Implementation of

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem’ (2004) 7(1) *Journal of International Economic Law* 73, 80.

<sup>14</sup> Nicholas Vincent, ‘TRIP-ING Up: The Failure of TRIPS Article 31bis’ (2020) 24(1) *Gonzaga Journal of International Law* 3, 22.

<sup>15</sup> TRIPS Agreement, Article 31bis (3).

<sup>16</sup> Mike Gumbel, ‘Is Article 31bis Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System’ (2008) 22(1) *Temple International and Comparative Law Journal* 161, 170

ability of pharmaceutical and vaccine sector development in Africa.”<sup>17</sup>

While the provision does not explicitly address compulsory licensing, the proposed regional cooperation to enhance economies of scale for pharmaceutical products, under Article 21(3) of the Protocol, aims to leverage Article 31bis of the TRIPS Agreement. This is further strengthened by article 21(4) of the Protocol, which requires State Parties to report annually to the Committee on Intellectual Property Rights (IPRs), which then reviews and passes recommendations.<sup>18</sup>

It is crucial to strike a balance in the approach to compulsory licensing, aligning it with the imperative to build regional pharmaceutical production. Aggressive use of compulsory licensing does not necessarily facilitate technology transfer or attract foreign direct investment (FDI).<sup>19</sup> The Protocol mandates regional cooperation for local pharmaceutical production, while the specifics of compulsory licensing are left to individual State Parties. The forthcoming annex on patents is expected to provide clarity on the mechanisms for achieving this delicate equilibrium, recognising the nuanced relationship between compulsory licensing and the essential goal of establishing a robust regional pharmaceutical industry.<sup>20</sup>

#### *Public Health Emergencies and Local Production of Pharmaceuticals*

Article 21 of the Protocol not only mandates State Parties to ensure that their legislation facilitates access to essential public health products; it also addresses public health emergencies and local pharmaceutical production. It grants State Parties extensive authority to undertake any actions necessary to safeguard the interests of essential public health during emergencies, including epidemics and pandemics.<sup>21</sup> This provision stands out for its comprehensive scope compared with international IP treaties, imposing no restrictions on the authority of State Parties to protect public health interests during emergencies.<sup>22</sup> Moreover, the provision implies that the emergency need not be exclusively

public health-related but could encompass any situation posing a potential threat to the public health interests of the state. In essence, this provision aligns with the spirit of the Doha Declaration, emphasising that the TRIPS Agreement should not impede members from taking necessary measures to safeguard public health.<sup>23</sup>

State Parties are mandated to collaborate and harmonise their policies, focusing on local production and the development of regional value chains for pharmaceuticals and vaccines, among other items. This collaboration involves coordinating national policies on IPRs, innovation, trade, industry, and health to foster the local production of crucial healthcare tools, including vaccines and therapeutics.<sup>24</sup> Furthermore, the Protocol mandates cooperation in developing regional value chains essential for the competitiveness and sustainability of the vaccines and pharmaceutical sector. This obligation aligns with the AfCFTA’s objective of ensuring IP cooperation within the free trade area, as outlined in Article 4(c) of the AfCFTA Agreement.

This provision is distinctive to the AfCFTA IP Protocol, and sets it apart from the TRIPS Agreement. Drafted during a pandemic that underscored the crucial need for local production in addressing public health emergencies, the Protocol’s inclusion of local production is commendable. However, the implementation mechanism of this obligation should be clearly outlined in the annex and executed in accordance with State Parties’ commitments under the TRIPS Agreement and other international IP treaties.

Regarding technology transfer, although the Protocol identifies contribution to technology transfer as a specific objective in Article 2(2), it lacks a dedicated provision aimed at facilitating its implementation. The sole mention of technology transfer pertains to the need for cooperation among State Parties to enhance the capabilities of their IP offices to promote technology transfer.<sup>25</sup> While cooperation is essential in this area, there is a pressing need for substantive obligations in this regard, especially

<sup>17</sup> AfCFTA Draft IP Protocol, Article 21(3).

<sup>18</sup> AfCFTA Draft IP Protocol, Article 21(4) & 21(5).

<sup>19</sup> Duncan Matthews, ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem’ (2004) 7(1) *Journal of International Economic Law* 73, 80.

<sup>20</sup> Caroline Ncube, ‘Intellectual Property and the African Continental Free Trade Area: Lessons and Recommendations

for the IP Protocol’ (2022) 21(2) *Journal of International Trade Law and Policy* 105.

<sup>21</sup> AfCFTA Draft IP Protocol, Article 21(1).

<sup>22</sup> *Ibid.*

<sup>23</sup> Doha Declaration on TRIPS and Public Health, Paragraph 4.

<sup>24</sup> AfCFTA Draft IP Protocol, Article 21(3).

<sup>25</sup> AfCFTA Draft IP Protocol, Article 24(C).

considering the significant capacity gaps among AfCFTA member states.

African states have consistently expressed concerns about the inadequate execution by developed countries of technology transfer obligations under the TRIPS Agreement, as well as the absence of effective follow-up mechanisms to ensure the incentivisation of technology transfer.<sup>26</sup> As an African instrument designed to address IP issues that have been overlooked or insufficiently addressed globally, the Protocol should have included more substantive details to guarantee effective technology transfer among state parties.

### *Regulatory Review Exception*

The regulatory review exception, crucial for the introduction of pharmaceutical products to the market pending regulatory approval, plays a pivotal role in broadening access to affordable medications. By empowering generic drug manufacturers to initiate the marketing approval process during the innovator drug's patent term, it fosters competition and cost reduction. The exception's effectiveness hinges on the regulatory authority's determination of the safety and efficacy of generic drugs, with particular emphasis on their bio-equivalence and chemical equivalence to the innovator drug.<sup>27</sup> Significantly, the exception also acts as a deterrent to evergreening, curbing patent holders' attempts to artificially extend the product's patent term.<sup>28</sup>

In the context of the IP Protocol, State Parties are mandated to provide regulatory review exceptions for activities exclusively related to the development and submission of information for regulatory approval as required by the laws regulating the making, use, sale, or import of the product.<sup>29</sup> Studies underscore the substantial reliance of sub-Saharan Africa on imported medicines, constituting 70 to 90 percent of the pharmaceutical landscape, while the continent contributes a mere 3 percent to

global pharmaceutical production.<sup>30</sup> Acknowledging this dependence, the inclusion of the regulatory review exception could promote the local production of generic drugs.

However, State Parties determine the conditions for permitting such exception, according to the product in question. This could include various forms of generic pharmaceuticals, such as synthesised drugs or biologics, in addition to local production or import of drugs that have already been approved and marketed.<sup>31</sup> As the Protocol emphasises the need to enhance local production of pharmaceuticals, the exception serves as a vital tool to facilitate the production and marketing of generic drugs within the AfCFTA.

### *TRIPS Flexibilities under the AfCFTA IP Protocol*

The preamble of the AfCFTA Agreement affirms the right of State Parties to regulate and achieve legitimate policy objectives, including those related to public health.<sup>32</sup> The provision of flexibilities, tailored to the diverse needs and economic development levels of State Parties, is a guiding principle within the AfCFTA.<sup>33</sup> The AfCFTA Protocol on Trade in Goods also encourages the provision of flexibilities to other State Parties based on levels of economic development or individual specificities to be determined by other AfCFTA members. Similarly, the AfCFTA Protocol on Trade in Services, under Article 7, provides for State Parties to accord flexibilities, such as transitional periods, to other members on a case by case basis.<sup>34</sup>

Under the IP Protocol, there is an emphasis on leveraging flexibilities provided by international IP instruments. Article 23 underscores cooperation among State Parties to facilitate the utilisation of flexibilities under international agreements, focusing on public health, food security, agriculture, and nutrition.<sup>35</sup> Notably, however, unlike certain regional patent instruments such as the East African Community (EAC) Protocol on Public Health, the

<sup>26</sup> TRIPS Agreement, Article 66. See also World Trade Organization. Implementation of Article 66.2 of the TRIPS Agreement: Decision of the Council for TRIPS of 19 February 2003, WTO doc. IP/C/28, 20 February 2003.

<sup>27</sup> Viviana Munoz Tellez, 'Bolar Exception' in Carlos Correa & Reto Hilty, *Access to Medicines and Vaccines: Implementing Flexibilities under International Intellectual Property Law*, (Springer, 2022) 135.

<sup>28</sup> Tolulope Anthony Adekola, *Regional Cooperation, Intellectual Property Law and Access to Medicines: A Holistic Approach for Least Developed Countries* (Routledge, Abingdon 2024) 54.

<sup>29</sup> AfCFTA Draft IP Protocol, Article 12(3)(e).

<sup>30</sup> Alison Buckholtz, 'Inside Africa's Push to Make its Own Medicines' (World Bank, June 2021) <<https://www.ifc.org/en/stories/2021/africa-pharma-manufacturing-hubs-en>> accessed 10 August 2025.

<sup>31</sup> Tellez (n 23).

<sup>32</sup> AfCFTA Agreement, Preamble.

<sup>33</sup> Ibid, Article 5(d).

<sup>34</sup> African Union. African Continental Free Trade Area Protocol on Trade in Services. 21 March 2018, Article 7(b).

<sup>35</sup> AfCFTA Draft IP Protocol, Article 23(f).

AfCFTA IP Protocol does not obligate or urge State Parties to fully utilise these flexibilities. Under the EAC Protocol, EAC partner states are required to implement public health measures through the utilisation of public health-related WTO TRIPS flexibilities and the approximation of national IP legislation.<sup>36</sup> This omission by the AfCFTA IP Protocol fails to align with the approaches of some regional economic communities (RECs) that encourage members to fully utilise flexibilities concerning patents and public health. Notwithstanding, it is expected that the utilisation of flexibilities will be separately addressed in annexes for each area of IPRs, particularly patents. In addition, the Protocol incorporates major flexibilities. State Parties retain the authority to determine areas such as patentability criteria, and their prerogative to take any measures to address public health emergencies is duly enshrined.<sup>37</sup> LDC State Parties benefit from transitional arrangements for full compliance, a special exemption for pharmaceutical patents and test data.<sup>38</sup> A regional regime of parallel importation is adopted.<sup>39</sup> Additionally, state parties are obligated to domesticate Article 31bis, highlighting a comprehensive, but also flexible, approach to IP governance within the AfCFTA.<sup>40</sup>

#### *Potential Relationship Between the Protocol and Regional Bodies*

In accordance with the “preservation of the *acquis*” principle emphasised in Article 5 of the AfCFTA Agreement, the preamble of the AfCFTA IP Protocol acknowledges the achievements of regional IP institutions in the development, administration, protection, and promotion of IPRs across the continent. Article 33(2) further underscores the importance of cooperation and technical assistance among subcontinental bodies, particularly the African Regional Intellectual Property Organization (ARIPO) and African Intellectual Property Organization (OAPI). However, uncertainties persist regarding the nature and structure of the relationship between the AfCFTA IP Office and these regional organisations. While the annex could clarify this,

potential resistance from these organisations to relinquish IP registration responsibilities may lead the AfCFTA IP Office to prioritise support over replacement of their core functions.

Similar provisions apply to regional economic communities (RECs). The AfCFTA IP Office is mandated to collaborate with RECs in the protection and promotion of IPRs across Africa. Article 33 of the Protocol also promotes technical assistance for, and capacity building with, RECs, though the specifics of these relationships remain to be clarified in the annex. A crucial element addressing the relationship between the Protocol and RECs is Article 36 of the AfCFTA Agreement, which asserts the primacy of the Protocol over other regional IP agreements in cases of conflict.<sup>41</sup> Thus, the Protocol’s provisions take precedence over those of RECs where inconsistencies arise, unless the REC has achieved a level of integration sufficient to allow its members to uphold IP standards within that REC.<sup>42</sup>

#### IV. DISCUSSION

The AfCFTA IP Protocol presents a unique opportunity to address the ongoing tensions between IPRs and public health matters without undermining the international system. By focusing on the intersection of these two critical areas, the Protocol aims to create a framework that supports both the protection of IP and the promotion of public health initiatives among its member states. This is essential in light of the growing recognition that public health should not be compromised by stringent IP regulations.<sup>43</sup>

The Protocol incorporates significant provisions that empower AfCFTA members to utilise IP as a tool for enhancing public health. This innovative strategy is particularly relevant in the context of the COVID-19 pandemic, during which the need for accessible pharmaceuticals and health solutions became paramount. The protocol encourages member states to harness their IP rights to promote domestic pharmaceutical production in order to respond swiftly to health emergencies and ensure that vital medical products are available when needed most.

<sup>36</sup> East African Community. Regional Pharmaceutical Manufacturing Plan of Action 2012-2016 (later 2017-2027). EAC Secretariat; 2017.

<sup>37</sup> Ibid, Article 12.

<sup>38</sup> Ibid, Article 35(3).

<sup>39</sup> Ibid, Article 7.

<sup>40</sup> Ibid, Article 12(3).

<sup>41</sup> AfCFTA Agreement, Article 36.

<sup>42</sup> AfCFTA Agreement, Article 19(2).

<sup>43</sup> Christopher May & Susan K Sell, *Intellectual Property Rights: A Critical History*, (Lynne Rienner, 2005), 115.

However, despite its progressive intentions, the Protocol lacks key details that are crucial for its effective implementation. For instance, it does not adequately address procedural matters related to compulsory licensing or include provisions for relevant patent waivers during emergencies. These omissions highlight the need for further development of the Protocol's annexes, which should aim to rectify these substantive issues and provide clearer guidelines for member states. To this end, it is crucial that the Protocol establish comprehensive guidelines for compulsory licensing procedures, enabling member states to swiftly implement these processes during public health emergencies. Incorporating specific provisions for patent waivers during crises, such as the Doha Declaration and the COVID Waiver, would facilitate rapid access to essential medicines by circumventing legal obstacles. Furthermore, research shows that, despite numerous references to public health-related flexibilities in the TRIPS Agreement and other global IP frameworks, awareness and utilisation of these remain minimal in the region.<sup>44</sup> Therefore, it is essential to implement training programs for IP offices and stakeholders to enhance their understanding and application of the Protocol's provisions, not only regarding the use of flexibilities but also in areas such as technology transfer and IP licensing.

North Africa accounts for approximately 40 percent of Africa's pharmaceutical production across the continent, while a group of eight major manufacturing hubs—Algeria, Egypt, Ghana, Kenya, Morocco, Nigeria, South Africa, and Tunisia—collectively accounts for 80 percent of local output.<sup>45</sup> These eight countries have relatively advanced research and development infrastructure, a favorable investment climate, and greater manufacturing capacity compared with other, less-developed African peers. It is crucial not only to clearly outline effective technology transfer mechanisms among member states, but also to establish suitable transitional arrangements for less developed member states to ensure gradual full compliance with the Protocol's obligations. For example, under the IP

rights chapter of the Regional Comprehensive Economic Partnership (RCEP), state parties receive grace periods based on their financial, technical, and administrative capabilities to gradually implement these obligations.<sup>46</sup> Given the regional disparities and concentration of pharmaceutical production, the protocol's annexes should consider similar arrangements to facilitate equitable compliance among member states.

## V. CONCLUSION

The approach taken by the AfCFTA IP Protocol allows states to actively exercise their rights under international IP law—specifically the TRIPS Agreement—to address public health challenges. However, this strategy also represents a missed opportunity to consolidate African arguments for leveraging IP in the interest of public health. By not comprehensively outlining these rights and their application, the Protocol could fall short of fully empowering member states to advocate for health as a priority within the broader context of IP rights. As the Protocol evolves, it will be crucial to ensure that it addresses these gaps to maximise its impact on public health in Africa.

The Protocol serves as a crucial tool for addressing public health concerns within the AfCFTA as it integrates public health-related provisions aimed at encouraging innovation in the sector. These provisions encompass aspects such as local pharmaceutical production, regional value chains, access to and transfer of technology, and the protection of test data, along with the adoption of a regional exhaustion regime. Such measures are instrumental in enhancing investment and progressively reshaping the health landscape. However, the specifics of how these provisions are to be implemented must be sufficiently addressed in the annexes.

## VI. REFERENCES

### Table of Legislation

- African Union, Agreement Establishing the African Continental Free Trade Area (AfCFTA Agreement), 30 May 2019.

<sup>44</sup> Olugbenga Ajani Olatunji, Regional Approach to Boosting Local Pharmaceutical Manufacturing Capacity: A Critique of the East African Community Pharmaceutical Manufacturing Plan of Action, 73 *GRUR International* 11, 2024, 1036–1049.

<sup>45</sup> Africa Development Bank, *A New Frontier for African Pharmaceutical Manufacturing Industry*, 2022, 6.

<sup>46</sup> The Regional Comprehensive Economic Partnership is a Free Trade Agreement encompassing 15 member countries,

of which 10 are ASEAN members (Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam), 3 from East Asia (China, Japan, South Korea) and 2 Oceania countries (Australia, New Zealand). See <<https://www.dfat.gov.au/trade/agreements/in-force/rcep#:~:text=RCEP%20entered%20into%20force%20on,Indonesia%20on%20January%202023>> accessed November 04, 2025.

- African Union, Protocol to the Agreement Establishing the African Continental Free Trade Area on Intellectual Property Rights (Draft), 19 February 2023.
- African Union, Protocol to the Agreement Establishing the African Continental Free Trade Area on Trade in Services, 30 May 2019.
- World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994.
- World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 20 November 2001.
- Alison Buckholtz, 'Inside Africa's Push to Make its Own Medicines' (World Bank, June 2021) <https://www.ifc.org/en/stories/2021/africa-pharma-manufacturing-hubs-en> accessed on 10 August 2025.

### Table of Books

- Carlos Correa & Reto Hilty, *Access to Medicines and Vaccines: Implementing Flexibilities under International Intellectual Property Law*, (Springer, Cham 2022).
- Christopher May & Susan K Sell, *Intellectual Property Rights: A Critical History*, (Lynne Rienner, Boulder 2005).
- Tolulope Anthony Adekola, *Regional Cooperation, Intellectual Property Law and Access to Medicines: A Holistic Approach for Least Developed Countries* (Routledge, Abingdon 2024).

### Table of Journals

- Anna S.Y Wong, Clarke B. Cole & Jillian C. Kohler, 'TRIPS Flexibilities and Access to Medicines: An Evaluation of Barriers to Employing Compulsory Licenses for Patented Pharmaceuticals at the WTO' (2022) 168 *South Centre Research Paper* 28, 2022.
- Caroline Ncube, 'Intellectual Property and the African Continental Free Trade Area: Lessons and Recommendations for the IP Protocol' (2022) 21(2) *Journal of International Trade Law and Policy* 105, 2022.
- Duncan Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem' 7(1) *Journal of International Economic Law* 73, 2004.
- Martin Khor, 'Patents, Compulsory Licenses and Access to Medicines: Some Recent Experiences' *Intellectual Property Rights Series* 11, 2009.
- Mike Gumbel, 'Is Article 31bis Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System' 22(1) *Temple International and Comparative Law Journal* 161, 2008.
- Nicholas Vincent, 'TRIP-ING Up: The Failure of TRIPS Article 31bis' 24(1) *Gonzaga Journal of International Law* 3, 2020.

### Table of Other Materials Cited

- African Union, Assembly of the Union, Thirty-Sixth Ordinary Session, Assembly/AU/Dec. 839-