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# Compulsory Licensing for Pharmaceutical Access in East Africa: The Challenge of Kenya's Failure to Adopt Article 31*bis* of the TRIPS Agreement

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## Abstract

*Sub-Saharan Africa, including East Africa, grapples with profound public health challenges exacerbated by limited access to pharmaceuticals. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), enacted in 1995, introduced patent rights for pharmaceuticals, restricting generic production. Even so, Article 31 of the TRIPS Agreement permits compulsory licensing to facilitate cheaper generic versions, but this is underutilised by smaller economies like those in the East African Community (EAC) due to economic constraints. To help address this challenge, Article 31bis allows countries in a Regional Trade Agreement (RTA) to pool demand and import medicines collectively, thus boosting economies of scale. It also permits local manufacturing and re-export of pharmaceuticals within the RTA. The EAC qualifies for this mechanism, but many of its members lack the implementation legislation required to use the system. This paper focuses on the implications of Kenya's lack of such implementing legislation to medicine accessibility in the EAC. This is because it is well positioned, given its growing pharmaceutical sector, to potentially become a regional hub for medicine production and to attract foreign supplies. Although creating such legislation will not solve all the challenges around the usage of compulsory licenses, its creation is important to ensure the system is available to the EAC in its aspiration to increase the accessibility of medicines.*

**Keywords:** *Compulsory licensing, regional cooperation, access to medicines, East African Community, TRIPS Agreement Article 31bis*

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## I. Introduction

> *'…the fact that TRIPS flexibilities exist in the TRIPS Agreement is only half the story- the degree to which these flexibilities are incorporated into domestic legislation determines the precise scope of availability to countries seeking to protect legitimate domestic industries'.*[1]

Patent-holders are granted monopoly rights over the manufacture, use, offer for sale, sale and importation of their pharmaceutical inventions by virtue of Article 28 of the TRIPS Agreement.[2] The eight countries of the East African Community (EAC), Kenya, Burundi, Rwanda, Tanzania, Uganda, the Democratic Republic of Congo, South Sudan and Somalia, are party to the TRIPS Agreement by virtue of their membership in the World Trade Organisation.[3] This means that producing generic versions of the products to increase accessibility in the EAC was, as a general rule, prohibited when the TRIPS Agreement entered into force in 1995 (subject to the relevant transition periods granted to developing and least developed countries).[4]

However, the agreement also contains flexibilities, such as compulsory licensing, which provides countries' policy space to promote non-trade interests like protecting public health. Compulsory licensing is provided for in Article 31 which enables WTO Members to authorize the production of generic pharmaceuticals without authorization from a patent holder.[5] Article 31*bis* was introduced as an amendment to the TRIPS Agreement to address the limitations imposed by Article 31(f). Article 31(f) restricts the use of compulsory licensing to predominantly supplying the domestic market even when the production of pharmaceuticals was done to export to other countries.[6] Article 31*bis* waives

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1 Adekola T*, Regional cooperation, intellectual property law and access to medicines: a holistic approach for least developed countries*, Routledge, New York, 2024, 41.

2 Article 28, *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 UNTS 299.

3 The TRIPS Agreement is a 'multilateral agreement' meaning that all the Members of the WTO must have agreed to it before joining or remaining in the WTO framework.

4 World Trade Organisation, 'Overview: The TRIPS Agreement' -< https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#:~:text=The%20TRIPS%20Agreement%2C%20which%20came,-multilateral%20agreement%20on%20intellectual%20property> on 17 July 2024. The transition periods allowed for TRIPS compliance in Article 65 (2) to developed countries was 1 January 1996 (a year after the agreement came into force) and 1 January 2000 for developing countries. In addition, least developed countries were granted an extension until 1 January 2034 as seen in World Trade Organisation, 'Responding to least developed countries' special needs in intellectual property' 16 October 2013 -< https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm> on 17 July 2024.

5 Article 31, Agreement *on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 UNTS 299.

6 Article 31(f), *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 UNTS 299.

the restriction of Article 31(f), enabling the export of adequate quantities of medicines to countries with insufficient manufacturing capabilities.[7] This ensures that importing countries can access necessary medicines even if they are patent protected in exporting countries. [8]

In addition, recognizing challenges such as poor economies of scale and limited purchasing power and local production in smaller economies when acting individually, paragraph 3 of Article *31bis* envisions the collective usage of compulsory licenses by countries of a Regional Trade Agreement (RTA). It waives the requirement in Article 31(f) for RTAs where at least half of its membership is composed of Least Developed Countries (LDCs), such that an exporting country would be able to export or re-export one hundred percent of the pharmaceuticals it produced or imported under a compulsory license to other countries of the region. The EAC is one such RTA recognized by the WTO.[9] This regional initiative is especially important due to the wide array of challenges individual EAC states face when attempting to deploy national strategies to address the accessibility of medicines. These issues include, high transaction costs, limited organizational and administrative skills, and vulnerability to the legal and economic pressures imposed by patent holders and their governments, to name a few.[10]

Although the value of this *regional* initiative cannot be understated, one country appears particularly useful in advancing the goals of improved access to medicines of the EAC. This can be attributed to its relatively larger contributions to increasing economies of scale and its promising future in local production.

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7 Article 31*bis* (1) and (3), *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 UNTS 299.

8 It is important to note that Article 31*bis* has certainly been received with scepticism. For instance, some critics argue that the amendment is insufficient as it is restricted to RTAs where at least half the countries that are members are on the United Nations list of least developed countries. As a whopping 5 of the 6 qualifying RTAs are in Africa, developing countries from other regions of the world (including South America and the Caribbean) are excluded from the potential benefits. See Gumbel M, 'Is Article *31bis* enough' 22 *Temple International Comparative Law Journal* 1, 2008, 163. In addition, the system has seen limited use (only once when known as the Paragraph 6 System) leading to its characterisation as 'stagnated'. See Igbokwe and Tosato, 'Access to medicines and pharmaceutical patents: fulfilling the promise of TRIPS Article 31bis',91 *Fordham Law Review* 5, Pennsylvania, 2023, 58. Igobkwe and Tosatso also identify four broad categories of the barriers to the usage of the system. They are governmental and corporate interferences, obtrusions caused by domestic laws and free trade agreements, procedural complexities, and economic challenges. They conclude that economic issues, including high costs, low profitability in small markets and susceptibility to patentees lowering prices, are primary impediments to utilising Article 31*bis*.

9 Word Trade Organisation, 'Regional Trade Agreements Database' -<https://rtais.wto.org/UI/PublicSearchByMemberResult.aspx?membercode=404> on 3 January 2023.

10 Adekola T*, Regional cooperation, intellectual property law and access to medicines: a holistic approach for least developed countries*, 131.

Kenya, due to its large pharmaceutical market size and the rate of its growth is said to act as an 'anchor country', attracting more suppliers by making their investment that much more lucrative.[11] In this way, it makes a significant contribution in bettering the economies of scale of the EAC. In addition, it leads the region in pharmaceutical manufacturing with an established industry that already satisfies a significant portion of its local demand.[12] The development of local manufacturing capacity is crucial to reduce the dependence on foreign suppliers in developed countries, which proved unreliable during the COVID-19 pandemic,[13] ensure health security and guarantee faster and more flexible responses during health crises.[14]

For the reasons highlighted above, it is especially disappointing that despite accepting the Article 31*bis* amendment,[15] Kenya lacks implementing legislation adopting it into domestic law. This is problematic because such legislation is needed domestically to enable a country to utilize the flexibility.[16] Acceptance of the amendment is only useful at the international plane by denoting that a Member formally recognises that other WTO Members ought to be able to use the system, should they choose to.[17] This paper will therefore concentrate on detailing the gravity of Kenya's lack of such legislation to the access to medicines in the EAC. The hypothesis of this study is that Kenya's failure to enact implementing legislation for Article 31*bis* hampers the EAC from maximizing the regional mechanism outlined in Article 31*bis*(3).

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11 United Nations Economic Commission for Africa, Situational *analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 11.

12 Adekola T*, Regional cooperation, intellectual property law and access to medicines: a holistic approach for least developed countries*, 88.

13 Adekola T*, Regional cooperation, intellectual property law and access to medicines: a holistic approach for least developed countries*, 88.

14 Adekola T*, Regional cooperation, intellectual property law and access to medicines: a holistic approach for least developed countries*, 85.

15 World Trade Organisation, 'Amendment of the TRIPS Agreement' -<https://www.wto.org/english/tratop_e/TRIPS_e/amendment_e.htm> on 19th October 2023.

16 Adekola T*, Regional cooperation, intellectual property law and access to medicines: a holistic approach for least developed countries*, 41. See also Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation', World Trade Organisation Economic Research and Statistic Division, Staff Working Paper ERSD-2015-07, 2015, 4 https://www.wto.org/english/res_e/reser_e/ersd201507_e.pdf on 19 July 2024 and World Trade Organisation, 'Members' law implementing the 'Paragraph 6' system' -<https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm> on 28 November 2023.

17 World Trade Organisation, 'How to accept the Protocol Amending the TRIPS Agreement' -<https://www.wto.org/english/tratop_e/trips_e/accept_e.htm#:~:text=On%206%20December%202005%2C%20the,came%20into%20force%20in%201995> on 27 November 2023.

This section serves as the introduction to the study. Part II examines the effectiveness of the regional mechanism in Article 31*bis*(3) in enhancing medicine accessibility within the EAC, emphasizing economies of scale and collaborative solutions. Part III discusses the importance of enacting local legislation to activate these mechanisms, distinguishing between international acceptance and domestic implementation of amendments. It further highlights the consequences of Kenya's current lack of implementing legislation for Article 31*bis* (3), limiting the EAC's ability to fully utilize regional compulsory licensing.

Part IV evaluates Kenya's pivotal role within the EAC's framework, emphasizing its potential contributions to local production, pooled procurement, and economies of scale. This analysis leads to the conclusion that implementing legislation within Kenya is crucial for maximizing regional compulsory licensing for pharmaceutical access in the EAC. Part V provides recommendations for policymakers and stakeholders to prioritize enacting implementing legislation in Kenya to enhance the benefits of regional compulsory licensing. Finally, Part VI summarizes the findings and underscores the critical role of domestic legislation in facilitating effective regional cooperation and improving access to medicines within the EAC.

## II. Assessing the Value of a Compulsory License Under Article 31*bis* in Achieving Access to Medicines in the EAC RTA

Within the framework of the World Trade Organization (WTO), specific types of regional agreements may enable Members to utilize certain flexibilities. In paragraph 3 of Article 31*bis*, RTAs with at least half their membership being least developed countries (LDCs) are addressed. They are relieved from complying with the restriction in Article 31 (f) that calls for compulsory licenses for pharmaceuticals to be used primarily to supply the domestic market.[18] Importantly, it leverages their regional status to allow their member countries to issue compulsory licenses to import or produce pharmaceuticals and then freely re-export or export them to their fellow members who need them.[19] As such, it provides a collaborative approach to addressing similar health needs within a particular region.

[18] Article 31*bis* (1), *Agreement on trade-related aspects of intellectual property rights*, 15 April 1994, 1869, UNTS 299.

[19] Article 31*bis* (1), *Agreement on trade-related aspects of intellectual property rights,* 15 April 1994, 1869 UNTS 299.

The EAC is an RTA recognised by WTO.[20] It is a regional intergovernmental organization composed of eight states from East Africa.[21] These states are Kenya, Tanzania, Uganda, Rwanda, the Democratic Republic of Congo, Somalia, Burundi and South Sudan.[22] Established by the Treaty for the Establishment of the East African Community on 7th July 2000,[23] it creates policies and programs for cooperation on various fields including political, social and cultural, for the mutual benefit of the Partner States.[24]

The first section of this part offers a history of the access to medicines campaign aiming to help the reader understand the intersection of intellectual property law, specifically the TRIPS regime, and public health. The second section discusses the regional mechanism under Article 31*bis* 3 demonstrating the challenges of single state action and justifying regional cooperation.

### *i. A Brief History of Access to Medicines and the TRIPS Regime*

#### a. Access to medicines before the TRIPS Agreement

A wide range of diseases have afflicted the developing world. These include HIV/AIDS, tuberculosis (TB), malaria, acute respiratory infections and sexually transmitted diseases.[25] Before the TRIPS Agreement came into effect on 1st January 1995, governments had much more freedom to implement policies to tackle such public health concerns.[26] This is because the previous international intellectual property rules were not quite as demanding of countries.[27] For instance, the Paris Convention for the Protection of Industrial Property of 1883, spoke to rules of priority and national treatment, leaving governments

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20 Word Trade Organisation, 'Regional Trade Agreements Database (Kenya)' -<https://rtais.wto.org/UI/PublicSearchByMemberResult.aspx?membercode=404> on 3 January 2023.

21 East African Community, 'Overview of the EAC' -<https://www.eac.int/overview-of-eac> on 28 December 2023.

22 East African Community, 'Overview of the EAC' -<https://www.eac.int/overview-of-eac> on 28 December 2023.

23 East African Community, 'History of the EAC' -<https://www.eac.int/eac-history> on 28 December 2023. Also see Article 2, *Treaty for the establishment of the East African Community*, 7 July 2000, 2144 UNTS 255.

24 Article 5 (1), *Treaty for the establishment of the East African Community*, 7 July 2000, 2144 UNTS 255.

25 Médecins Sans Frontières Briefing for the 5th WTO Ministerial Conference, *Doha Derailed: A Progress Report on TRIPS and Access to Medicines*, 20 October 2003, 6.

26 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions' 10 (4) *Journal of International Economic Law*, 2007, 927.

27 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 927.

the right to formulate patent systems.[28] Some chose to weaken patent protection specifically for pharmaceuticals,[29] others chose to use compulsory licensing to override exclusive patent rights,[30] and some even denied patent protection over pharmaceuticals altogether.[31] These efforts encouraged competition between big pharmaceutical companies and their cheaper generic versions allowing poor countries to have access to affordable medicines.[32]

Due to the weaker patent rules, non-legal factors such as the availability of active pharmaceutical ingredients, the reverse-engineering capacity of generic producers and the pricing policies of both big pharmaceutical companies and generic companies were key deciding factors in the accessibility of medicines in the developing world. [33]

### b. Access to Medicines During TRIPS Implementation

The mid-1990s saw the triumph of the pharmaceutical industry and certain rich countries with the establishment of a system of rules for the protection of intellectual property through the TRIPS.[34] As part of the package, prospective members of WTO had to accept that upon joining, they were obliged to afford intellectual property protection, extending it to pharmaceutical goods.[35]

The full effects of TRIPS implementation were felt following the end of the transition periods allowed to developing country Members (that is until 1 January 2000)[36] by Article 65 (2) of the TRIPS Agreement.[37] As such, develop-

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28 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 927.

29 Anderson H, 'We can work it out: co-op compulsory licensing as the way forward in improving access to anti-retroviral drugs' 16, *Boston University Journal of Science and Technology Law*, 2, 2010, 174.

30 Anderson H, 'We can work it out: co-op compulsory licensing as the way forward in improving access to anti-retroviral drugs', 175.

31 Anderson H, 'We can work it out: co-op compulsory licensing as the way forward in improving access to anti-retroviral drugs', 174.

32 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 928.

33 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 927 and 928.

34 'Patents versus patients five years after the Doha Declaration', Oxfam International, Oxfam Briefing Paper Number 95, 2006, 5 -< https://oxfamilibrary.openrepository.com/bitstream/handle/10546/114562/bp95-patents-versus-patients-doha-141106-en.pdf; jsessionid=7862826E298EB59C81BEDD460C3CBF93?sequence=1> on 25 May 2024.

35 'Patents versus patients five years after the Doha Declaration', 5.

36 World Trade Organisation, 'Frequently asked questions about TRIPS [ trade-related aspects of intellectual property rights ] in the WTO' -< https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm> on 21 May 2024.

37 Article 66 (1), *Agreement on trade-related aspects of intellectual property rights*, 15 April 1994,1869 UNTS 299.

ing countries combating serious health issues were now obliged to enforce the patent rights and protections of pharmaceutical companies in their territories.[38] The result was the limitation of the freedom governments had to act amid public health crises. For instance, Article 27 of the TRIPS Agreement made it clear that *all* inventions, including pharmaceutical products, were available for patenting so long as they satisfied the patentability criteria.[39] This thus brought an end to governments' ability to discriminate between different industries in patent protection for purposes of enabling access to inexpensive medication.

Another provision, Article 28, authorised a patent holder to prevent unauthorised third parties from making, using, offering for sale, selling and importing patented products or the results of patented processes.[40] These are considered the 'exclusive rights' of the patent holder.[41] This provision would grant monopoly power to pharmaceutical companies by enabling them to essentially kill competition from cheaper generics. This is because such generics would effectively be violating Article 28 of the TRIPS Agreement, either by their creation through the patented process or by their equivalence to a patented product.[42] This enabled pharmaceutical companies to sell using a 'low volume, high margin' strategy that would allow them to reap the most profit.[43] This, of course, was problematic to the world's poor who could not afford life-saving medication.[44]

Further, Article 30 would limit the kinds of exceptions that can be taken on patents to those that 'do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner'.[45] Article 31 would also confine the use of a compulsory license by creating requirements such as prior negotiation with a patent holder, the limitation of the scope and duration of the license and the notorious predominant-domestic use requirement that is the subject of this paper.[46]

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38 Article 1 (1), *Agreement on trade-related aspects of intellectual property rights*, 15 April 1994, 1869 UNTS 299.

39 Article 27, *Agreement on trade-related aspects of intellectual property right*s, 15 April 1994, 1869 UNTS 299.

40 Article 28 (1), *Agreement on trade-related aspects of intellectual property rights*, 15 April 1994, 1869 UNTS 299.

41 See the title of Article 28, *Agreement on trade-related aspects of intellectual property rights,* 15 April 1994, 1869 UNTS 299.

42 Article 28, *Agreement on trade-related aspects of intellectual property rights,* 15 April 1994, 1869 UNTS 299.

43 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 970.

44 'Patents versus patients five years after the Doha Declaration', 5.

45 Article 30, *Agreement on trade-related aspects of intellectual property rights*, 15 April 1994, 1869 UNTS 299.

46 Anderson H, 'We can work it out: co-op compulsory licensing as the way forward in improving access to anti-retroviral drugs', 175.

## c. Access to Medicines Leading up to the Doha Rounds of Negotiation

The World Health Organisation (WHO) is the primary institution responsible for addressing the public health needs of developing countries.[47] However, the WTO has become 'a central focus' due to its development of rules governing patents while neglecting the implications of its rules to the health sector. [48] As a result, the WTO was forced to reckon with the impact of TRIPS implementation on public health in the late 1990s and early 2000s.[49]

At a special meeting of the TRIPS Council, on behalf of the African Group, Zimbabwe highlighted the global inequalities in access to antiretroviral drugs (ARVs).[50] While up to 11 million lives were lost annually in the less developed world due to HIV/AIDS, their afflicted counterparts in the industrialized world experienced significantly fewer deaths due to their access to the ARVs.[51] The African Group stated that the Members needed to clarify the room that governments have to adopt and apply the TRIPS flexibilities. This was said to be the sort of reassurance governments needed to take actions such as compulsory licensing and parallel importation without fear of litigation nationally or at the WTO or political intimidation from the pharmaceutical industry and governments.[52]

Eventually, the result of the special meeting was the creation of the Doha Declaration on the TRIPS and Public Health ('Doha Declaration') of November 2001. In this declaration, all WTO Members agreed that the TRIPS Agreement does not and should not prevent any Member form taking measures to protect public health.[53] Further, it reaffirmed a Member's right to 'use*, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose',* the purpose being public health, specifically access to medicines for all).[54]

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47 Abbott F, 'The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO' 5 *Journal of International Economic Law*, 2002, 504.

48 Abbott F, 'The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO',505.

49 'Patents versus patients five years after the Doha Declaration', 5.

50 World Trade Organisation Council for Trade-Related Aspects of Intellectual Property Rights, *Special discussion on intellectual property and access to medicines*, IP/C/M/31, 18-22 June 2001, 3.

51 World Trade Organisation Council for Trade-Related Aspects of Intellectual Property Rights, *Special discussion on intellectual property and access to medicines*, IP/C/M/31, 18-22 June 2001, 3.

52 World Trade Organisation Council for Trade-Related Aspects of Intellectual Property Rights, *Special discussion on intellectual property and access to medicines*, IP/C/M/31, 18-22 June 2001, 4.

53 World Trade Organisation Ministerial Conference, *Declaration on the TRIPS Agreement and public health,* WT/MIN (01)/DEC/2, 20 November 2001, para.4.

54 World Trade Organisation Ministerial Conference, *Declaration on the TRIPS Agreement and public health*, WT/MIN (01)/DEC/2, 20 November 2001, para.4.

However, the Doha Declaration did not resolve the difficulty faced by developing countries lacking sufficient manufacturing capacity in using compulsory licenses due to the requirement in Article 31(f) that a compulsory license be used primarily to serve the domestic market.[55]

### d. Access to Medicines Following the Doha Declaration on TRIPS and Public Health

The solution that was eventually adopted is commonly referred to as the 'Paragraph 6 System' in reference to its roots in the Doha Declaration.[56] It waived the obligation in Article 31(f) for pharmaceuticals and thus, eased the use of compulsory licenses for their export allowing up to one hundred percent of their export.[57]. During negotiations of this solution, Members were split over three key issues: the scope of diseases, eligible countries, and the TRIPS articles to be addressed.[58]

The governments of major pharmaceutical companies such as the United States, lobbied to restrict the scope of diseases.[59] They argued that: (i) the Doha Declaration limited the scope by making reference to the specific ailments of HIV/AIDS, tuberculosis and malaria,[60] (ii) that from an investment perspective, it is important to restrict the goods for which a compulsory license can be obtained as such licenses may discourage investment into research and development (R&D) and, (iii) that from a health perspective, without revenue for Research and Development (R&D), in the long term, the society would lose as medicines to treat diseases would not be produced.[61]

On the other hand, developing countries stressed that even though their immediate concerns were from HIV/AIDS, tuberculosis and malaria, the

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55 World Trade Organisation, 'TRIPS and public health' -< https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> on 3 January 2024.

56 World Trade Organisation, 'TRIPS and public health' -< https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> on 3 January 2024.

57 World Trade Organisation General Council, *Implementation of paragraph 6 of the Doha declaration on the TRIPS Agreement and public health: decision of the general council of 30 August 2003*, WT/L/540 and Corr.1, 1 September 2003.

58 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health' 99 (2) *American Journal of International Law*, 2005, 327, 334 and 338.

59 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 329.

60 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 327 And 328.

61 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 329.

accessibility of medicines for many other diseases was still of concern.[62] They argued that it did not make much public health sense to address a handful of diseases and ignore the rest since the patients of both sets of diseases needed access to affordable medicine.[63]

Developed Members such as the United States and the European Union also wanted to restrict the countries that were eligible to import under the system.[64] As the system was to address countries with limited or insufficient manufacturing capacity, they suggested various methods of classifying countries to weed out those who could and could not use the system.[65] For instance, they proposed using statistics on national income and production capabilities.[66] Nevertheless, developing countries were intent on preventing the creation of distinctions among them regardless of the difference in their development and production capabilities.[67] In the end, the 'Paragraph-6 System' gave special treatment to least developed countries by presuming them to have insufficient manufacturing capacity and thus, allowing them to automatically use the system. Other countries would have to notify the TRIPS Council their assessment proving their lack of or limited manufacturing capacity.[68]

On the final issue, there were largely two proposals to address the problem under Article 31(f). One was to use the limitation of exclusive rights clause under Article 30, and the other was to waive or amend Article 31.[69] Non-Governmental Organisations (NGOs) and developing countries favoured an Article 30 approach and argued that Article 31 has many 'bureaucratic impediments' in the form of its requirements. In addition, it left room for the intervention of patent holders in both the importing and exporting countries where their approval or consultation was required.[70]

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62 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 328.

63 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health',328.

64 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 334.

65 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 335.

66 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 335.

67 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 334.

68 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 336.

69 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 338 and 339.

70 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 339.

Pharmaceutical industries and their home governments, arguing for an Article 31 approach, highlighted the legal uncertainty of using Article 30. Without specific legal rules guiding its use, how was a patent holder to know when legitimate or illegitimate actions were being undertaken?[71] Eventually, the African Group and other countries ended up settling for an Article 31 approach in part because the United States was unlikely to accept an Article 30 approach.[72] It is appreciated that developing countries were also split on which approach to take and as a result, the alignment of the European Union with the United States and other countries gave proponents of the Article 31 approach more leverage.[73]

Initially, the 'Paragraph 6 System' solution operated as an interim waiver.[74] Through the decision of 6th December 2005, Members acting through the General Council, adopted the Protocol amending the TRIPS Agreement making it a permanent part of the TRIPS Agreement.[75] This amendment is now known as Article 31*bis*.

### *ii. The Value of Regional Cooperation Under Article 31bis (3)*

#### a. The General Value of a Compulsory License

A compulsory license refers to the use of a patented product or process without the authorization of the patent holder.[76] It allows governments directly or indirectly, through third parties, to make, use, offer for sale, sell or import pharmaceuticals.[77] Through the Doha Declaration, WTO Members reaffirmed their ability to use TRIPS flexibilities *to the full,* for example through compulsory licenses to help address public health problems, ensuring the accessibility of medicines for all.[78]

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71 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 339.

72 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 340.

73 Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health', 341.

74 World Trade Organisation General Council, *Implementation of paragraph 6 of the Doha declaration on the TRIPS Agreement and public health: decision of the general council of 30 August 2003*, WT/L/540 and Corr.1, 1 September 2003.

75 World Trade Organisation General Council, *Amendment of the TRIPS Agreement: decision of 6 December 2005,* WT/L/641, 8 December 2005.

76 Article 31, *Agreement on trade-related aspects of intellectual property rights,* 15 April 1994, 1869 UNTS 299.

77 Article 31 and 28, *Agreement on trade-related aspects of intellectual property rights*, 15 April 1994, 1869 UNTS 299.

78 World Trade Organisation Ministerial Conference, *Declaration on the TRIPS Agreement and public health: decision of the general council of 30 August 2003*, WT/MIN (01)/DEC/2, 20 November 2001, Paragraph

The main use of a compulsory license to countries appears to be its usefulness in price negotiations with patent holders.[79] The price of medicines is a crucial factor affecting their accessibility as it determines whether existing medicines can be afforded by poor patients.[80] Whether through actual imposition or the threat of imposition, governments are able to incentivize pharmaceutical companies to reduce the prices of their medicines.[81] If they accept, developing countries are able to provide more affordable patented medicines to their populations. If they do not, governments are able to seek out generic manufacturers who would produce medicines and supply their market at better rates. As such, by prompting competition, a compulsory license can help developing countries attain more affordable medicines.[82]

In addition, a compulsory license can also be used to encourage local production.[83] During negotiations on the terms of the license, a government can offer higher prices to the patent holder on the condition that they contribute to local manufacturing capacity.[84] The local producer could either directly set up shop in the relevant country or partner with an existing local entity to promote production.[85] In this way, the better remuneration package could boost production capabilities in the less developed world.

## b. The Failure of Single State Action and Justifying Regional Cooperation

While implementing TRIPS flexibilities such as compulsory licensing, Members can choose to act individually or collectively. Cross-border collaboration

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79 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 970. See also Owoeye O, *Intellectual property and access to medicines in Africa: a regional framework for access,* Routledge, New York, 2019, 54, and Anderson H, 'We can work it out: co-op compulsory licensing as the way forward in improving access to anti-retroviral drugs', 185.

80 See Abbott F, 'The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO', 472 and Anderson H, 'We can work it out: co-op compulsory licensing as the way forward in improving access to anti-retroviral drugs',174.

81 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 970.

82 Abbott F, 'The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO', 472.

83 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 970.

84 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 975 and 976.

85 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 975 and 976.

is not a novel strategy to improve the accessibility of pharmaceuticals and has demonstrated substantial effectiveness in various contexts. For instance, partnerships between the private and public spheres as well as the cooperation of governments has yielded notable results, including those orchestrated by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), UNITAID and the Global Alliance for Vaccines and Immunizations (GAVI).[86]

When acting individually, states face a wide array of economic, legal and technical constraints.[87] Economically speaking, most developing countries have small market sizes individually, and little disposable income to spend on goods making it less profitable for pharmaceutical companies or their generic competitors.[88] The legal constraint is the case-by-case approach that compulsory licenses under TRIPS operate which requires each Member to go through the same legal and administrative barriers in each case which increases their transaction cost.[89] The technical constraints involves the limited coordination within and between developing-country governments when engaging in compulsory licenses,[90] and defensive actions by patent holders to cut off access to sources key active ingredients.[91]

Some have classified the issues involved in single state action to implement TRIPS flexibilities into two levels. Musungu, Villanueva and Blasetti argue that states face hurdles first when incorporating the flexibilities into their laws,[92]

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86 Lee KS, Ming LC, Lean QY, Yee SM, Patel R, Taha NA and Kassab YW, 'Cross-border collaboration to improve access to medicine: association of Southeast Asian nations perspective' 9 *Journal of Epidemiology and Global Health June 2,* 2019, 94.

87 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 972.

88 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 972. See also Adekola T, 'Regional mechanism under Doha paragraph 6 system—the largely untested alternative route for access to patented medicines '15 A*sian Journal of WTO & International Health Law and Policy* 61, 2020, 66.

89 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 972.

90 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 973.

91 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 972 and 973.The authors explain that patentees gain additional power through the limited nature of key active ingredients. Big pharmaceutical companies typically located in developed countries own or control such resources. As a result, patentees retaliate by attempting to 'choke off access to such sources of supply when a state attempts to employ compulsory licensing to obtain patented pharmaceuticals.

92 Musungu S, Villanueva S, and Blasetti R, 'Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks' South Centre, April 2004, 23 https://www.southcentre.int/wp-content/uploads/2022/11/Bk_2004_Utilizing-TRIPS-Flexibilities-for-Public-Health-Protection_EN.pdf on 22 May 2024.

such as the lack of technical expertise and the over-reliance on models from developed countries.[93] Second, when implementing supporting legal and policy measures, states encounter challenges like insufficient research and manufacturing capacities, inadequate regulatory infrastructure and pressure from bilateral agreements and TRIPS-plus measures.[94] These constraints limit the countries' ability to effectively utilise TRIPS flexibilities and hence undermines efforts to improve accessibility of medicines.

Other authors justify regional cooperation by turning to the difficulty faced by low-income countries in regulating and approving medicines due to their technical and infrastructural constraints,[95] the advantage of 'regional negotiation' whereby a group of countries leverage their potential purchasing power,[96] and the usefulness of price transparency among countries when negotiating with producers and suppliers.[97] These scholars propose that the above constraints can be solved by combining national legal and policy efforts with regional ones.[98] Regional action would help ease constraints by enabling countries to share experience, expertise as well as allowing them to pool resources and information on suppliers and medicinal products.[99] In addition, it would create economies of scale, motivating patent holders to engage in business with them.[100]

93 Musungu S, Villanueva S, and Blasetti R, 'Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks', 24 and 25.

94 Musungu S, Villanueva S, and Blasetti R, 'Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks', 25-31.

95 Adekola T, 'Regional mechanism under Doha paragraph 6 system—the largely untested alternative route for access to patented medicines', 67.

96 Mercurio B, 'Resolving the public health crisis in the developing world: problems and barriers of access to essential medicines' University of New South Wales, Faculty of Law Research Series, Paper Number 23, 2007, 25 -<https://law.bepress.com/cgi/viewcontent.cgi?article=1025&context=unswwps-flrps> on 22 May 2024.

97 Mercurio B, 'Resolving the public health crisis in the developing world: problems and barriers of access to essential medicines', 25.

98 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 972 and 973, and Musungu S, Villanueva S, and Blasetti R, 'Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks', xiv and 3. See also Adekola T, 'Regional mechanism under Doha paragraph 6 system—the largely untested alternative route for access to patented medicines', 66- 69.

99 Musungu S, Villanueva S, and Blasetti R, 'Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks', xiv.

100 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 973.

### c. Regional Cooperation Under Article 31bis(3) in Combination with Pooled Procurement and Regional Pharmaceutical Centres

Abbott and Reichman envision enhancing the benefits of regional cooperation under Article 31*bis* (3), by combining it with pooled procurement strategies and the use of regional centres.[101] Such a system would first involve developing and least developed countries coming together to form an RTA in the proportions elaborated by Article 31*bis*. At this stage, they may opt for a pooled procurement strategy allowing them to collectively bargain for the supply of lower priced medicines with patent holders.[102] This would be beneficial even without the formation of a central organizing authority tasked with considering the terms of a compulsory license and negotiating on their behalf.[103]

The countries can also opt to create a regional centre which Abbott and Reichman refer to as a Regional Pharmaceutical Supply Centre (RPSC), to agree on what essential medicines are to be obtained and coordinate the procurement.[104] They argue that this would be useful in overcoming the constraints faced by individual governments. Such constraints include the 'predictable lack of coordination among developing country governments as well as the patchwork of measures and counter measures to obtain affordable medicines which do not seem to generate much accessibility of medicines of poor countries 'as a whole'.[105] Such a centre would involve the input of all countries and as such, its Board of Directors would be composed of health ministers of the constituent countries.[106]

The governments would then issue compulsory licenses under Article 31*bis* (2) and submit them to the RPSC, who would pool them together into a

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101 See Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', and Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centres' Duke University Law School, Paper prepared for Seminar on Intellectual Property Arrangements: Implications for Developing Country Productive Capabilities in the Supply of Essential Medicines for United Nations Conference on Trade and Development, 2006.

102 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 974.

103 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 973.

104 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 974.

105 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 973.

106 Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centres', 21.

regional compulsory license.[107] Thereafter, the RPSC would invite tenders from pharmaceutical companies and their generic counterparts to satisfy the regional demand.[108] This presents a better incentive for suppliers as the various markets are combined to generate economies of scale.[109]

The centre should ordinarily aim to obtain a voluntary agreement with the patent holders for the supply of the medicines, in the interest of preserving both the interests of the region and the right holder.[110] The system would be attractive to a patent holder as it would enable it to cement its market share region-wide and guard against competition overtaking it in the near future.[111] However, if the patent holder declines to supply at an affordable price, the RPSC can invite generic manufacturers to supply the drugs under the compulsory licenses.[112]

In addition to increasing their bargaining power during price negotiations, RPSCs could also be used to generate local production which is one goal of Article 31*bis* (3).[113] To do so, during price negotiations, they could offer a more rewarding remuneration package for pharmaceutical companies that agree to set up local production within one of the countries of the region.[114] This could be through direct efforts or through partnering with local partners that already operate in the area.[115] Again, should the companies turn this offer down, the RPSC can approach generic manufacturers with a similar deal.[116] Abbott and Reichman believe that such efforts could lead to the creation of local manufacturing capacity akin to that developed in India during the transition period before TRIPS provisions were required to be implemented.[117]

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107 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 974.

108 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 974.

109 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 973.

110 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 975.

111 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 975.

112 Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centres', 23.

113 Article 31*bis* (3), *Agreement on trade-related aspects of intellectual property rights*, 15 April 1994, 1869 UNTS 299.

114 Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centres', 22 and 23.

115 Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centres', 22 and 23.

116 Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centres', 23.

117 Abbott F and Reichman J, 'The Doha round's public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions', 976.

Returning to Article 31*bis*(3), the supply could be coordinated for each country, or to one specific country who is allowed to re-export them to the rest under this provision.

The advantages of compulsory licenses under Article 31*bis* can further be enhanced in the EAC using strategies such as pooled procurement and regional centres. This presents an excellent opportunity for the EAC to enhance the access to essential medicines for its poorer citizens.

## III. Examining the Place of Domestic Legislation in Implementing Compulsory Licensing under Article 31*bis* of the TRIPS Agreement

Implementation refers to putting something into practice or into effect. In the context of the WTO, it may be defined as all the 'modalities, mechanisms, and instruments that assist in the application of the WTO Agreements'.[118] To implement the various WTO Agreements, scholars have considered two 'distinct but interactive' levels of implementation.[119] The first is at the institutional level, whereby the focus is on the WTO enforcing the implementation mechanisms and methods set out by the WTO Agreements.[120] This includes mechanisms such as capacity building, monitoring, supervision and enforcement all aimed at steering WTO Members towards compliance with the agreements.[121]

The second level is concerned with Members and how they embed the commitments within the agreements into their national legal systems.[122] This Part of the paper is concerned with the second level, termed as the national level. It explores the relevance of Member's domestic legislation in implementing Article 31*bis*. In doing so, it first discusses how TRIPS provisions, in general, are to be given effect domestically, highlighting the need for domestic legislation to realise the benefits of the TRIPS provisions. Thereafter, it narrows down to how the implementation of Article 31*bis* was envisioned. It concludes by discussing the consequences of the lack of implementing legislation to breathe the flexibility that is Article 31*bis,* to life.

118 Zhang X, 'Implementation of the WTO Agreements: framework and reform' 23 *North western Journal of International Law & Business* 2, 2003, 384.

119 Zhang, 'Implementation of the WTO Agreements: framework and reform', 384.

120 Zhang, 'Implementation of the WTO Agreements: framework and reform', 384.

121 Zhang, 'Implementation of the WTO Agreements: framework and reform', 387.

122 Zhang, 'Implementation of the WTO Agreements: framework and reform', 384.

### *i. Understanding TRIPS: A Prelude to Article 31bis Implementation*

The TRIPS Agreement refers to Members' enactment of '*laws, regulations, policies, judicial and administrative decisions* to provide for TRIPS 'subject matter' (the availability, scope, acquisition, enforcement, and abuse prevention of intellectual property right)'.[123] Due to its broad coverage of the implementation of multiple commitments, this section will discuss Article 1.1 to further highlight how the WTO envisioned the application of TRIPS.

Article 1.1, the very first provision, is entitled 'Nature and Scope of Obligations'.[124] In its first sentence, it mandates the Members to 'give effect' to the commitments in the TRIPS Agreement.[125] The panel in *China- Intellectual Property Rights* has interpreted it to mean that it creates a 'basic obligation' on Members.[126] The next sentence states that Members can adopt *laws* that go above the protections required by the TRIPS Agreement, subject to the condition that those protections do not contravene the TRIPS provisions.[127] The same Panel explained this to mean that Members are free to implement a higher standard, subject to the in-built condition.[128] This clarifies that TRIPS is only a minimum standards agreement.[129]

Through the third sentence of Article 1.1, Members have the flexibility to choose the method of implementing their obligations on condition that it is appropriate within its legal system and practice.[130] Panels have interpreted this final sentence to indicate that although the TRIPS has no intention of harmonising *laws* between Members,[131] it does not grant them the freedom to implement a lower standard.[132] Rather, it grants Members the freedom to determine the appropriate means of implementing the TRIPS provisions.[133]

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123 Article 63 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

124 Article 1 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

125 Article 1 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

126 China - *Measures affecting the protection and enforcement of intellectual property rights, DS362, WTO Panel,* 2009, para.7.513.

127 Article 1 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

128 *China - Measures affecting the protection and enforcement of intellectual property rights*, DS362, WTO Panel, 2009, para.7.513.

129 *China - Measures Affecting the protection and enforcement of intellectual property rights,* DS362, WTO Panel, 2009, para.7.513. See also *Australia - Certain measures concerning trademarks, geographical indications and other plain packaging requirements applicable to tobacco products and packaging*, DS467, WTO Panel, 2013, para.7.2682.

130 Article 1 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

131 *Australia - Tobacco plain packaging*, DS467, WTO Panel, 2018, para.7.2682.

132 *China - Measures affecting the protection and enforcement of intellectual property rights*, DS362, WTO Panel Report, 2009, para.7.513.

133 *China - Measures affecting the protection and enforcement of intellectual property rights*, DS362, WTO Panel Report, 2009, para.7.513.

From the plain text and the above interpretations of Article 1.1, it appears as though the treaty negotiators envisioned at least the use of national laws to provide for the subject matter of the TRIPS Agreement. In addition, past jurisprudence, for instance in cases such as *EC- Trademarks and Geographical Indications,* confirm that *many* laws can be used to address the same intellectual property standards, even those that were not created specifically to provide for Intellectual Property Right (IPR) protection.[134]

In *EC- Trademarks and Geographical Indications*, the complainant, the United States, claimed that the European Communities Regulation 2081/92 did not provide for national treatment for geographical indications, and was therefore insufficient in its protection of pre-existing trademarks that are similar to geographical indications.[135] While the Panel agreed that the Regulation's protection was insufficient, it did not find a TRIPS violation because the EC (European Community) had other laws addressing the matters such as the unfair competition laws of EC member States.[136] It made it clear that the EC, and other Members, are not obliged to ensure a particular regulation implemented a TRIPS provision where it had other measures to do the same.[137]

However, it is not only hard law that is accepted. In *India- Patents (US),*[138] India presented "administrative instructions" (directions to the Patent Office)[139] as its method of implementation and the Panel agreed that "Members are free to determine how best to meet their obligations under the TRIPS within the context of their own legal systems."[140] Another provision of the TRIPS, Article 63.1, confirms the flexibility by providing that Members are to publish *laws, regulations, final judicial decisions* and *administrative rulings of general applicability* that

134 *European Communities — Protection of trademarks and geographical indications for agricultural products and foodstuffs,* DS174, WTO Panel, 2006, para.7.750.

135 *EC — Trademarks and geographical indications (US), DS174,* WTO Panel, 2006, para.7.747.

136 *EC — Trademarks and geographical indications (US)*, DS174, WTO Panel, 2006, para.7.750.

137 *EC — Trademarks and geographical indications (US)*, DS174, WTO Panel, 2006, para.7.746.

138 *India — Patent protection for pharmaceutical and agricultural chemical products*, DS50, WTO Appellate Body, 1998.

139 *India — Patent protection for pharmaceutical and agricultural chemical products*, DS50, WTO Appellate Body, 1998, 60. The Appellate Body decision stated that, "…According to India, pursuant to these "administrative instructions", the Patent Office has been directed to store applications for patents for pharmaceutical and agricultural chemical products separately for future action pursuant to Article 70.8, and the Controller General of Patents Designs and Trademarks ("the Controller") has been instructed not to refer them to an examiner until 1 January 2005."

140 *India — Patent protection for pharmaceutical and agricultural chemical products*, DS50, WTO Appellate Body, 1998, 59. However, India did not effectively justify the appropriateness of this method to fulfil its mailbox obligations.

pertain to the subject matter of TRIPS.[141] This highlights the methods in which negotiators envisioned Members implementing the TRIPS provisions.

As such, we are pointed to laws, regulations, practices, and decisions as methods to implement the TRIPS commitments. As will be seen in the following sections, the Members also consider the use of laws and regulations to realise compulsory licensing under 31*bis* within their own legal systems.

### *ii. The Content and Implementation of TRIPS Article 31bis*

Articles 30, 31 and 31*bis* serve as exceptions to the exclusive patent rights enshrined in Article 28 of the TRIPS Agreement.[142] As such, they provide a mechanism for Members to pursue non-trade policy interests without violating their TRIPS commitments. Article 31 is considered to hold significant importance in the relationship between patents and access to affordable patented products.[143] This is because it may be used to enable accessibility of patented items that is hindered through the monopoly pricing power granted by patents.[144] Compulsory licensing is a mechanism enabled by Article 31, allowing governments to authorise the use of inventions without the authorisation of patent holders before the expiry of the patent.[145]

The provision does not explicitly define situations for granting a compulsory license except in the case of semiconductor technology.[146] It is suggested that treaty negotiators preferred to keep potential instances of use open while implementing strict safeguards.[147] The requirements listed between Article 31(a)-(l) specify the conditions under which a compulsory license may be granted (the safeguards).[148] These provisions mandate that before resorting to a compulsory license, applicants must attempt to negotiate a voluntary license except in certain

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141 Article 63 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

142 Articles 30, 31 and 31*bis, Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

143 Wong A, Cole C and Kohler J, 'TRIPS flexibilities and access to medicines: an evaluation of barriers to employing compulsory licenses for patented pharmaceuticals at the WTO' South Centre, Research Paper Number 168, 2022, 7.

144 Wong A, Cole C and Kohler J, 'TRIPS flexibilities and access to medicines: an evaluation of barriers to employing compulsory licenses for patented pharmaceuticals at the WTO', 7.

145 Articles 31, *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

146 Articles 31, *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

147 Gervais D, *The TRIPS Agreement: drafting history and analysis*, 2 ed, Sweet & Maxwell, London, 2003, 250.

148 Articles 31*, Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

instances.[149] The Member must also ensure that the patent holder receives adequate remuneration.[150] Moreover, the compulsory license must be non-exclusive, non-assignable and primarily issued to supply the domestic market.[151] Daniel Gervais, who served as a member of one of the Negotiating Groups during the creation of TRIPS,[152] considers the safeguards a 'detailed checklist' for the Members.[153]

As seen earlier, to address the limitations of Article 31 on the accessibility of medicines to developing countries, Article 31*bis* took effect in 2017[154] as an amendment to Article 31.[155] In its annex, several procedural requirements are given for the use of Article 31*bis*. They include: (i) general notification of intent to use the system by importing Members (aside from LDCs) to the TRIPS Council; (ii) specific notifications of importing Members detailing the pharmaceutical products in need, their insufficient manufacturing capacity,[156] and a confirmation that it intends to grant a compulsory license where a pharmaceutical is patented in its territory; and (iii) a notification from exporting Members to the TRIPS Council, with information such as the quantity, destination and product features of the shipment.[157]

By 2017, two thirds of WTO Members had accepted the amendment.[158] However, acceptance and implementation are concepts that are 'entirely

[149] These instances are the existence of national emergency or other circumstances if extreme urgency. According to Article 31 (b) the requirement to seek a voluntary license may be waived in such situations.

[150] Articles 31 (h), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

[151] Articles 31 (d), (e) and (f), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

[152] Gervais D, *The TRIPS Agreement: drafting history and analysis*, viii.

[153] Gervais D, *The TRIPS Agreement: drafting history and analysis*, 250.

[154] World Trade Organisation, 'Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017)' -< https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm> on 28 November 2023.

[155] World Trade Organisation, 'Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017)' -< https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm> on 28 November 2023.

[156] This only applies if the Member is not a LDCs as LDCs are presumed to have insufficient manufacturing capacity as per the TRIPS appendix to Article 31*bis*.

[157] Annex to Article 31*bis*, *Agreement on trade-related aspects of intellectual property rights*, 15 April 1994, 1869 UNTS 299.

[158] World Trade Organisation, 'How to accept the Protocol Amending the TRIPS Agreement' -< https://www.wto.org/english/tratop_e/trips_e/accept_e.htm#:~:text=On%206%20December%202005%2C%20the,came%20into%20force%20in%201995> on 27 November 2023.

distinct'.[159] *Acceptance* is the expression of a Member's consent that WTO Members are entitled to use the amendment to issue compulsory licenses.[160] It is merely the 'formal recognition' that Members should be able to use the system if they wish to do so.[161] Acceptance is done through depositing an instrument of acceptance with the Director General of the WTO.[162] When, on the other hand, Members *implement* legislation, they are putting procedures in place to actually use it.[163] This legislative action provides a legal basis to act either exclusively as an exporter or importer of pharmaceuticals, or as both.[164] Thus, it is possible for a Member to accept the amendment, but not to adopt implementing legislation that allows it to use it.[165]

In his quantitative research on the topic, Kampf identifies the varying timelines between Member's acceptance and implementation of Article 31*bis*.[166] There are Members who first accept the amendment and then later execute implementing legislation.[167] This has been the favoured approach with the majority of the Members that have accepted the amendment.[168] Some

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159 World Trade Organisation, 'How to accept the Protocol Amending the TRIPS Agreement' -< https://www.wto.org/english/tratop_e/trips_e/accept_e.htm#:~:text=On%206%20December%202005%2C%20the,came%20into%20force%20in%201995> on 27 November 2023.

160 World Trade Organisation, 'How to accept the Protocol Amending the TRIPS Agreement' -< https://www.wto.org/english/tratop_e/trips_e/accept_e.htm#:~:text=On%206%20December%202005%2C%20the,came%20into%20force%20in%201995> on 27 November 2023.

161 Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation', 14 -15. See also World Trade Organisation, 'How to accept the Protocol Amending the TRIPS Agreement' -< https://www.wto.org/english/tratop_e/trips_e/accept_e.htm#:~:text=On%206%20December%202005%2C%20the,came%20into%20force%20in%201995> on 27 November 2023..

162 Article X (7), *Marrakesh agreement establishing the world trade organisation*, 15 April 1994, 1868 UNTS 3.See also World Trade Organisation, 'How to accept the Protocol Amending the TRIPS Agreement' -< https://www.wto.org/english/tratop_e/trips_e/accept_e.htm#:~:text=On%206%20December%202005%2C%20the,came%20into%20force%20in%201995> on 27 November 2023.

163 World Trade Organisation, 'How to accept the Protocol Amending the TRIPS Agreement' -< https://www.wto.org/english/tratop_e/trips_e/accept_e.htm#:~:text=On%206%20December%202005%2C%20the,came%20into%20force%20in%201995> on 27 November 2023.

164 Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation', 4. See also World Trade Organisation, 'Members' law implementing the 'Paragraph 6' system' -<https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm> on 28 November 2023.

165 World Trade Organisation, 'How to accept the Protocol Amending the TRIPS Agreement' -< https://www.wto.org/english/tratop_e/trips_e/accept_e.htm#:~:text=On%206%20December%202005%2C%20the,came%20into%20force%20in%201995> on 27 November 2023.

166 Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation', 5.

167 Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation', 6-7.

168 Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members'

Members opt to only accept the amendment but do not implement it.[169] Others simultaneously accept the amendment and implement it, while the remaining adopt implementing legislation and only later do they formally accept it.[170]

### *iii. The Consequences of the Lack of Implementing Legislation*

As part of the TRIPS Agreement, Article 31*bis* prevents a Member from being challenged at the WTO by another Member for its invocation of a compulsory license under the terms of 31*bis*.[171] However, it is domestic legislation that would enable a Member to use the system. This is because compulsory licensing serves as an exception to exclusive patent rights granted in the law and thus, needs express enabling legislation to be undertaken.[172] As alluded to in the previous section, without implementing legislation, sufficient existing legislation or soft law instruments that can incorporate Article 31*bis*, actors lack the basis to act either as exporters, importers, or both under 31*bis*.[173] Members without such legislation are unable to issue compulsory licenses 'despite the permissibility of this flexibility under the TRIPS Agreement'.[174]

Currently, ninety-five percent of WTO Members (one hundred and fifty-five of one hundred and sixty-four) have been found to have legislation implementing Article 31 (not Article 31*bis*).[175] This allows them to issue compulsory licenses, but are limited in doing so, primarily for domestic supply, under Article 31(f).[176] As such, in Member States where implementing legislation is lacking, this quantitative restriction under Article 31(f) remains the status quo.

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implementing legislation', 5. At the time Kampf published this piece (July 2015) 37 of the 50 Members who accepted the amendment followed this approach.

169 Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation', 5.

170 Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation', 5.

171 Wong A, Cole C and Kohler J', TRIPS flexibilities and access to medicines: an evaluation of barriers to employing compulsory licenses for patented pharmaceuticals at the WTO' South Centre, Research Paper 168, 2022, 10 -< https://www.southcentre.int/wp-content/uploads/2022/10/RP168_TRIPS-Flexibilities-and-Access-to-Medicines_EN.pdf> on 20 November 2023.

172 Wong A, Cole C and Kohler J', TRIPS flexibilities and access to medicines: an evaluation of barriers to employing compulsory licenses for patented pharmaceuticals at the WTO', 10.

173 Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation', 4.

174 Wong A, Cole C and Kohler J', TRIPS flexibilities and access to medicines: an evaluation of barriers to employing compulsory licenses for patented pharmaceuticals at the WTO', 10.

175 Wong A, Cole C and Kohler J', TRIPS flexibilities and access to medicines: an evaluation of barriers to employing compulsory licenses for patented pharmaceuticals at the WTO', 10.

176 Article 31 (f), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

This hampers their ability to maximise their importation or exportation of up to one hundred percent.

This status quo is particularly bad for RTAs such as the EAC because its Partner States often lack manufacturing capacity.[177] What this means is that in addition to being unable to rely on 31*bis* to import pharmaceuticals due to lacking the requisite legal basis, such countries may also be incapable of depending on Article 31. This is because, as importers, their access to medicines would still be hindered through the limited number of exporters willing and able to meet the condition in Article 31(f). It therefore becomes even more crucial for such countries to ensure they have implementing legislation to function as pharmaceutical importers.

## IV. Assessing Kenya's Contribution to the Regional Approach in Article 31bis (3) and the Gains Foregone by the EAC due to its Lack of Implementing Legislation

This Part examines the potential contribution of Kenya to regional initiatives aimed at enhancing the accessibility if medicines, relative to other EAC States. The purpose of doing so is to stress the importance of Kenya adopting implementing legislation to incorporate Article 31*bis* domestically. Without such legislation, the EAC stands to go without the immense benefits of its contribution to the accessibility of medication. Due to space, time and subject matter concerns, the regional plans to be discussed are those of the EAC and the African Continental Free Trade Area (AfCFTA).

### *i. Initiatives at the EAC and the AfCFTA Similar to or Incorporating the Article 31bis System*

Various initiatives within Africa are dedicated to the objective of pharmaceutical accessibility. However, due to constraints in both space and time, this article will primarily focus on exploring EAC initiatives, as they are central to the research focus. It is important to note that there is not much data comparing

[177] Appendix, A*greement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299. This section of the Agreement creates a presumption that LDCs lack manufacturing capacity. Most Members of the EAC are classified by the United Nations as LDCs so they would fall within this category. In addition, in Wong A, Cole C and Kohler J', TRIPS flexibilities and access to medicines: an evaluation of barriers to employing compulsory licenses for patented pharmaceuticals at the WTO', the authors breakdown into categories the Members with, without and with limited pharmaceutical manufacturing capacity. Rwanda is found to have limited capacity and Djibouti and Burundi completely lack it.

the contributions of one Partner State relative to another, in progressing the EAC's Article 31*bis* initiatives.

As such, to supplement this limited comparison, the AfCFTA-anchored Pharmaceutical Initiative will be examined. This is because of its analysis of Kenya's pharmaceutical sector and its potential successes in local production and pooled procurement initiatives. By examining Kenya's role in these initiatives, the author will illustrate the considerable advantage Kenya could contribute to the regional initiative at the EAC level.

### a) Regional Initiatives at the EAC

The EAC has founded various initiatives that address Article 31*bis* as well as the factors that enhance its benefits. For ease of reference, we can refer to the components of the 31*bis* system and enhancers as follows: (i) regional cooperation (the free export and re-export of the pharmaceuticals within RTAs under article 31*bis* (3), (ii) pooled procurement, (iii) local production and (iv) regional centres. These four aspects are relevant based on our discussion in Part II that revealed their usefulness in maximising the accessibility of medicines.

The EAC Partner States have agreed to undertake measures for the promotion of health in the Community in Article 118(e) of the Treaty for the Establishment of the East African Community (EAC Treaty). In furtherance of this, the EAC calls for the utilisation of *regional cooperation* under Article 31*bis* through the 2013 EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and The Approximation of National Intellectual Property Legislation.[178] This policy reviews the various TRIPS Flexibilities and the corresponding national legislation of EAC Partner States, showing inadequacies and pointing out where national reforms are needed.[179]

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[178] East African Community, *EAC regional intellectual property policy on the utilisation of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation,* 2013, 19. See Section 3.10 on Compulsory Licensing where EAC Partner States are advised to provide in their national law:

i) A provision authorising the export of up to 100% of the pharmaceuticals they produce. (A provision implementing or adopting Article 31*bis* which provides for this)

ii) Facilitate the use of Article 31*bis*. 3 which allows the export and re-export of medicines by one Partner State to another without having to abide by the notifications in annex 2 of Article 31*bis*.

iii) Facilitate the use of Article 31*bis* as an importing country, which requires certain notifications to the WTO.

[179] East African Community, *EAC regional intellectual property policy on the utilisation of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation,* 2013.

The EAC Health Protocol on Public Health Related WTO-TRIPS Flexibilities supports the Policy's goal, by mandating all states to draft guidelines and regulations implementing the Paragraph 6 Decision (now Article 31*bis*), both as eligible importing and exporting countries and calling on them to take advantage of the regional initiative in the provision.[180]

The Community is also keen on *pooled procurement*. As early as 2007, it worked together with the WHO Department of Technical Cooperation for Essential Medicines to conduct a situational analysis and feasibility study for the implementation of Regional Pooled Procurement of Medicines.[181] The study aimed to discern between Group Contracting and Central Contracting as the appropriate model of procurement for the EAC, noting that joint purchasing has been widely accepted to resolve issues such as the high prices of medicines and their poor quality.[182]

To stimulate *local pharmaceutical production*, the EAC has periodically drafted plans that assess current conditions and identify challenges and their proposed solutions. Currently, it has developed the 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017 -2027 that serves as a 'roadmap',[183] to guide states in building an effective regional pharmaceutical industry to satisfy national, regional, and international medicine needs.

The EAC lacks a singular *regional centre* to coordinate the joint purchasing and distribution of medicines. However, this makes sense because the appropriate form of pooled procurement for the region has been found to be Group Contracting.[184] This approach involves states jointly negotiating prices with select suppliers, agreeing to purchase from certain suppliers and then individually making such purchases.[185] As a result, the different states have different procurement organs. However, the various organs can coordinate their actions through the East Africa Public Procurement Forum which is an annual meeting of the states' procurement organs to agree on a procurement agenda.[186] Because

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180 Section 8 and 14, *EAC health protocol on public health related WTO-TRIPS flexibilities*, 2013.

181 East Africa Community, *A situational analysis and feasibility study on regional pooled bulk procurement of essential medicines and other health supplies in the East African Community partner states*, 2007, 8.

182 East Africa Community, *A situational analysis and feasibility study on regional pooled bulk procurement of essential medicines and other health supplies in the East African Community partner states*, 2007, 8.

183 East Africa Community, *2nd EAC regional pharmaceutical manufacturing plan of action*, 2017–2027, 1.

184 East Africa Community, *A situational analysis and feasibility study on regional pooled bulk procurement of essential medicines and other health supplies in the East African Community partner states*, 2007, 99.

185 East Africa Community, *A situational analysis and feasibility study on regional pooled bulk procurement of essential medicines and other health supplies in the East African Community partner states*, 2007, 98.

186 Public Procurement Regulatory Authority, 'About the East African Procurement Forum' -< https://ppra.go.ke/eapf/#programme> on 1 March 2024.

each EAC country has regional centres and procures pharmaceuticals separately, to demonstrate Kenya's contribution to the regional initiative in 31*bis,* the author will focus on Kenya's role in local production and pooled procurement instead.

### a. Initiatives at the AfCFTA

The AfCFTA-anchored Pharmaceutical Initiative was created in November 2019 through the collaboration of various organs including the United Nations Economic Commission, African Union Commission and the WHO.[187] It was launched to encourage the accessibility of pharmaceuticals continent wide by advancing both local production capacity and pooled procurement of medicines within Africa.[188] It explored the feasibility of its broader goals of accessibility and of the specific goals of local production and pooled procurement in a situational analysis and feasibility study. In doing so, it compared ten pilot countries to assess the value of their contributions to such regional plans.[189]

The ten pilot countries including Kenya and two other EAC members (DRC and Rwanda), are ranked based on different scales depending on whether the discussion is on pooled procurement or local production. The AfCFTA and the EAC both aim to enhance local production and pooled procurement. As earlier discussed, local production and pooled procurement are methods of enhancing the benefits of the 31*bis* system. Resultantly, Kenya's usefulness in local production and pooled procurement helps show its ability to advance the benefits of the 31*bis* system. As such, the results arrived at on these two factors by the AfCFTA may be a useful indicator to help us understand Kenya's contribution to the EAC when using the 31*bis* system.

However, it is important to note two things: First, this initiative does not place as much emphasis on the TRIPS system when creating its objectives. As such, we observe fewer discussions on Article 31*bis*. Second, the situational analysis and feasibility study of this initiative focused on maternal healthcare and childcare. Perhaps this is because the health of children and women has been considered the 'mainstay'[190] of a healthy society. Nevertheless, despite

[187] United Nations Economic Commission for Africa, *Showcasing the AfCFTA-anchored pharmaceutical initiative: lessons and experiences,* 2022, 3.

[188] United Nations Economic Commission for Africa, *Showcasing the AfCFTA-anchored pharmaceutical initiative: lessons and experiences,* 2022, 3.

[189] United Nations Economic Commission for Africa, *Situational analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 4.

[190] United Nations Economic Commission for Africa, *Situational analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 4.

this limitation on the scope of research, the relevant data given and analysed is general to the pharmaceutical industry, enabling us to apply it to the general field of pharmaceutical access.

The following sections will lay out the framework of comparison laid out in the situational analysis of AfCFTA study and present evidence of Kenya's relatively good contribution to the EAC's plans.

### *ii. Kenya's Contribution to Regional Initiatives such as the Article 31bis System*

The AfCFTA-anchored initiative assessment uses a framework created by drawing relevant parameters from existing literature, case studies and the databases of different regions and countries.[191] It considers various factors to draw conclusions on the feasibility of the countries in the initiative. However, throughout the study, it becomes apparent that a significant indicator of the benefits a country may offer to a regional trade area from local production and pooled procurement is often tied to the size of that country, as seen below.

The analysis underscores the advantageous position of larger countries such as Ethiopia and Kenya in undertaking local production. This is because of the corresponding rate of growth of their pharmaceutical industries.[192] These countries have enjoyed larger pharmaceutical industries and successes compared to the smaller countries in their region. However, it also notes that smaller countries like Rwanda, which prioritize the pharmaceutical sector in their national strategies, see decent rates of local production as well.[193] In addition, the study highlights the number of local pharmaceutical manufacturers producing essential medicines within each pilot country. This shows that some are countries are in a better position to undertake local production than others.[194]

When discussing pooled procurement in regional initiatives, larger countries like Ethiopia and Kenya are mentioned as potential 'anchor' countries due to their

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191 United Nations Economic Commission for Africa, *Situational analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 7.

192 United Nations Economic Commission for Africa, *Situational analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 57.

193 United Nations Economic Commission for Africa, *Situational analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 57.

194 United Nations Economic Commission for Africa, S*ituational analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 57.

size or large markets which attract investment.[195] Their participation in regional initiatives can thus increase the market size of the region[196] and, consequently, the economies of scale potential suppliers would enjoy from supplying medicines to the region.

Despite the relevance of size, the feasibility of pooled procurement also depends on each country's current strategy, capacities, and regional logistics opportunities for pooled procurement. Kenya is shown to do well under each of these factors. This is shown when the study expresses that Kenya aims to develop local industries not only for self-sufficiency but also for trade and industrialization, and leverages on enablers like political will, investment-friendly environments, and skilled workforces.[197]

The study concluded that Kenya is one of the three countries most capable of contributing to the success of the project (the AfCFTA-anchored Initiative) and, the establishment of local production and the use of pooled procurement generally.[198] This is advantageous for Kenya in meeting national medication needs. More importantly for this paper, it also benefits the EAC by providing an alternative to imported pharmaceutical goods and improving their bargaining power when negotiating as a group against foreign suppliers.

Some EAC countries have either similar or even higher populations than Kenya. For instance Tanzania has a population of approximately sixty-seven million and the Democratic Republic of Congo has a population of about one hundred and two million people, while Kenya's population is about fifty-five million.[199] Be that as it may, Kenya boasts the largest *pharmaceutical* market size (with about one hundred billion Kenyan Shillings of annual pharmaceutical expenditure),[200] and is regarded as the hub of pharmaceutical manufacturing in

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195 United Nations Economic Commission for Africa, Situational *analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 11.

196 United Nations Economic Commission for Africa, S*ituational analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa,* 2022, 11.

197 United Nations Economic Commission for Africa, Situational *analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 57.

198 See United Nations Economic Commission for Africa, S*ituational analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 50-58.

199 Worldometer, 'African Countries by Population (2024)' -< https://www.worldometers.info/population/countries-in-africa-by-population/#google_vignette> on 2 March 2024.

200 Machemedze R, Wade H, Kiiza A and Were N, 'Local production of essential health products in East and Southern Africa' Southern and Eastern African Trade, Information and Negotiations

the EAC.[201] As a result the benefits observed in the AfCFTA-anchored initiative may also apply here, whereby Kenya's pharmaceutical market size and prowess may allow it to act as an anchor country to the EAC to attract even more suppliers of medicines when pooling procurement.

In addition, Kenya has an overwhelming number of local pharmaceutical manufacturers within its territory relative to the other countries both in the pilot project and the EAC.[202] To illustrate, Kenya has between thirty to forty local manufacturers while Tanzania, Rwanda, and Uganda, have only six, one and nine respectively.[203] This demonstrates the relatively higher development of the local pharmaceutical production industry in Kenya in comparison to its Partner States in the EAC. This puts Kenya in a better position to eventually act as a supplier to other EAC countries of needed medicines and thus lessening the dependence on foreign suppliers of goods.

In conclusion, Kenya's pharmaceutical large market size and therefore its negotiating power, as well as its local production capacity make it especially useful in the EAC when employing the article 31*bis* system.

### *iii. The Consequences of Kenya's Lack of Implementing Legislation to Access to Medicines in the EAC*

By failing to amend its legislation to reflect Article 31*bis,* Kenya: (i) undermines the goal of the EAC of achieving accessible medicines in the region through joint efforts of its Partner States and (ii) limits Kenya's ability to locally produce or import pharmaceuticals with the intention of exporting or re-exporting them to other EAC country members.

The EAC Partner States manifest their general desire to collaborate by establishing 'co-operation for mutual benefit' as one of the fundamental principles in achieving their objective of widening and deepening their cooperation politically, socially, economically and beyond for their mutual benefit.[204] They express their intention to cooperate on matters health in Article 117 of the EAC

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Institute, Discussion Paper 128, 2022, 7 -<https://equinetafrica.org/sites/default/files/uploads/documents/EQdiss128%20EHP%20local%20production%20Nov22.pdf> on 28 February 2024.

201 Machemedze R, Wade H, Kiiza A and Were N, 'Local production of essential health products in East and Southern Africa', 7.

202 United Nations Economic Commission for Africa, S*ituational analysis and feasibility study for pooled procurement and local production of maternal, neonatal and child health products in 10 selected countries, quality-assured maternal and child health products in Africa*, 2022, 57.

203 Machemedze R, Wade H, Kiiza A and Were N, 'Local production of essential health products in East and Southern Africa', 7.

204 Articles 5 and 6, *The treaty for the establishment of the East African Community* (Act No 2 of 2000).

Treaty.[205] Specifically, the Partner States undertake to take joint action to prevent and control communicable and non-communicable diseases, control pandemics and epidemics of communicable and vector-borne diseases and to cooperate in facilitating mass immunisation and other public health campaign in the region.[206]

The specific joint efforts at the EAC as set out earlier in this part includes its Intellectual Property (IP) policy that addresses how Partner States can amend their legislation to 'fully utilise the Public Health-related WTO-TRIPS flexibilities'.[207] Another is the EAC Health Protocol that mandates countries to draft laws implementing Article 31*bis* into domestic law.[208] The rationale of joint efforts, generally, at the EAC is said to be the creation of larger markets that serve the purpose of attracting investment, expanding business, encouraging competition and innovation and creating employment.[209] In the context of Article 31*bis,* the benefits of a bigger market include increased economies of scale and thus increased interest of manufactures and investors in supplying the region with medicines and investing in local production as well as the improvement of the bargaining power of the region when negotiating as a block.[210] Thus, by failing to create implementing legislation, Kenya hampers the EAC's regional approach to increase the accessibility of medicines by fully maximising the TRIPS flexibilities of its member states, by using such approaches collectively instead of individually.

In addition, without such legislation, actors (manufacturers and suppliers in this case) lack the basis to act either as exporters, importers, or both under 31*bis*.[211] Kenya has incorporated the provisions of Article 31 of the TRIPS Agreement into its intellectual property laws, particularly the Industrial Property Act of 2001. This can be observed between Sections 72 to 78 of the Act which provides for compulsory licensing of patented products. In Section 75(2)(b), the Act creates as a condition for compulsory licensing, the use of the license predominantly to supply the domestic market. This mirrors the provision of the TRIPS Agreement in Article 31(f). However, Kenya has not adopted further

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205 Article 117, *The treaty for the establishment of the East African Community* (Act No 2 of 2000).

206 Article 118, *The treaty for the establishment of the East African Community* (Act No 2 of 2000).

207 East African Community, *EAC regional intellectual property policy on the utilisation of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation,* 2013, 11.

208 Section 8 and 14, *EAC Health Protocol on Public Health Related WTO-TRIPS Flexibilities*, 2013.

209 Kaahwa W, '*EAC Treaty and challenges to the community' East African Community,* Occasional Paper Number 3, 2003, 8 http://repository.eac.int/bitstream/handle/11671/24077/EAC%20Treaty%20and%20Challenges%20to%20the%20Community.pdf?sequence=1&isAllowed=y on 25 May 2024.

210 Please refer to part II (ii) (b) of this paper.

211 Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation', 4.

legislation providing for the waiver of this requirement as allowed by Article 31*bis*. This leads to the conclusion that Kenya has adopted Article 31 but has not yet adopted Article 31*bis*. This means that Kenya does not have the right to use Article 31*bis*.

Countries like Kenya whose IP laws reflect Article 31 but not Article 31*bis*, are stuck with the restrictions on compulsory licensing imposed by Article 31. For example, where implementing legislation adopting *31bis* is lacking, the quantitative restriction under Article 31(f) remains the status quo. This hampers Kenya's ability to maximize her importation or exportation of up to 100% of pharmaceutical products. In other words, should Kenya locally produce medicines with the intention of exporting them to its fellow EAC members, or import them from a foreign country to re-export them to other EAC states, she would have to adhere to the export restriction in Article 31(f) which requires the medicines to be used predominantly to supply the domestic market. This hinders the exploitation of pharmaceutical manufacturers within Kenya to supply the EAC with the needed medicines under a compulsory license. Without the enabling legislation, the suppliers would not be able to freely export and re-export to the other EAC members with the same public health problem as allowed by Article 31*bis*(3).

It is also worth noting that the AfCFTA protocol on intellectual property rights also supports the accessibility of pharmaceuticals, using mechanisms like Article 31*bis*. In fact, Article 12(3) (b) requires State Parties to ratify the amendment of Article 31*bis* to enable the export of pharmaceuticals under a compulsory license.[212] Furthermore, Article 21(3) calls on State Parties to ensure regional cooperation to increase economies of scale and to develop regional value chains to boost competitiveness and sustainability of pharmaceuticals in Africa.[213] As a result, Kenya's failure to enact implementing legislation adopting 31*bis* into law also undermines the objectives of the AFCFTA protocol to ensure accessibility of medicines.

## V. Recommendations

Before discussing the manner in which Kenya can adopt implementing legislation, it is appreciated that the various barriers to the accessibility of

[212] Article 12 (3) (b), *Protocol of the agreement establishing the African continental free trade area on intellectual property rights*, 18 February 2023.

[213] Article 21(3), *Protocol of the agreement establishing the African continental free trade area on intellectual property rights*, 18 February 2023.

medicines include both IP and non-IP related challenges such as lack of local manufacturing capacity, economies of scale, purchasing power and quality control.[214] As such, domesticating international IP rules cannot be the sole solution to enhance access; rather, a holistic approach composed of various tools, including IP rules, ought to be adopted.

Additionally, governments may face many obstacles as they consider implementing the amendment. Historically, during TRIPS implementation in the early 2000s, one key obstacle has included the application of political and economic pressure by pharmaceutical companies and developed countries with a stake in the industry.[215]

This pressure has included developed country Members concluding TRIPS-plus Free Trade Agreements, Bilateral Investment Treaties with national treatment rules and threats to turn to the dispute settlement body of the WTO or impose unilateral trade sanctions on developing country members.[216] Despite the flexing of political and economic muscle by countries like the United States and the European Union,[217] some developing countries have been able to resist such coercion. For example, collaboration between India, Brazil and South Africa assisted Brazil to deny TRIPS-plus provisions proposed by the US during the Free Trade Area of the Americas negotiations.[218] Furthermore, researchers assert that there was little evidence linking TRIPS implementation in the 2000s and certain kinds of pressure, due to the difference in the levels of TRISP flexibilities in developing countries experiencing similar levels of pressure.[219] The finer details of the factors impacting a government's ability to enact laws is beyond the scope of this paper, but would be a useful addition to the research conducted here which necessitates the creation of implementing legislation.

Considering the consequences of the lack of legislation implementing Article 31*bis* into domestic law, it is paramount for Kenya's IP laws to be amended. For reference on how Kenya could draft an amendment to its Industrial Property

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214 Adekola T*, Regional cooperation, intellectual property law and access to medicines: a holistic approach for least developed countries*, 4.

215 Deecre C, *The implementation game: the TRIPS Agreement and the global politics of intellectual property reform in developing countries*, Oxford University Press, Oxford, 2009, 150-186.

216 Deecre C, *The implementation game: the TRIPS Agreement and the global politics of intellectual property reform in developing countries*, 150- 159.

217 Deecre C, *The implementation game: the TRIPS Agreement and the global politics of intellectual property reform in developing countries*, 150- 159.

218 Deecre C, *The implementation game: the TRIPS Agreement and the global politics of intellectual property reform in developing countries*, 165.

219 Deecre C, *The implementation game: the TRIPS Agreement and the global politics of intellectual property reform in developing countries*, 165.

Act, we can turn to the respective laws and regulations of Albania, Singapore and Botswana as examples of countries who have implemented the amendment to act as exporters, importers and both, respectively.[220] Albania implements Article 31*bis* in Law No. 9947 of 7 July 2008 on Industrial Property.[221] In Article 50(3) courts, upon request, are entitled to grant compulsory licenses for the manufacture and sale of pharmaceuticals to importing countries, despite existing patent protections and supplementary protection certificates:[222]

> *'(3) On request, the court is entitled to grant a compulsory license in respect of patents and supplementary protection certificates relating to the manufacture and sell of pharmaceutical products, when such products are intended for export to importing countries in need of such products in order to address public health problems, subject to the implementing regulation'.*

The relevant law of Botswana is the Industrial Property Act, Act No. 8 of 2010.[223] It's Section 31 and 32 provide the legal basis for Botswana to act as importers and exporters under the Article 31*bis* system. Section 31 authorises a Minister to grant a government agency and other bodies or persons a compulsory license to use a patented product or process. More specifically, Section 31(3) mandates the exploitation of patents to be for the supply of the Botswana market *except* when Article 31*bis* applies, thus allowing the exportation to other countries in the quantities outlined in Article 31*bis*. Furthermore, Section 32(2) speaks to Botswana's ability to import under Article 31*bis*:

> *'(3) The exploitation of the patented invention under subsection (1) shall be for the supply of the domestic market in Botswana only, except where paragraph 1 or 3 of Article 31bis of the TRIPS Agreement applies'.*

Singapore's relevant law is the Patents Act 2005. Its Section 56(1A) enables the government and authorised third parties to import health products if the government has made the relevant notifications to the TRIPS Council as seen below:

> *'(1A) Without prejudice to the generality of subsection (1), subject to sections 60, 61 and 62, but notwithstanding any other section of this Act, the Government and any party authorised in writing by the Government may import any relevant health product, and do anything in relation to any relevant health product so imported, for or during a national emergency or other circumstances of extreme urgency, if the Government has given the Council for TRIPS a relevant notification in relation to the relevant health product'.*

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220 https://www.wto.org/english/tratop_e/TRIPS_e/par6laws_e.htm on 20th January 2024.

221 *Law No 9947 of 7 July 2008 on Industrial Property* (Albania).

222 Article 50 (3), *Law No. 9947 of 7 July 2008 on Industrial Property*, (Albania).

223 *Industrial Property Act* (Act No 8 of 2010).

It is important to note that some WTO Members consider the Article 31*bis* system to fit within their existing IP systems, such that no further implementing legislation is needed.[224] For instance, the Japan delegation, at the annual review of the Paragraph 6 System in October 2010 reported that its Patent Act, which provided for the grant of non-exclusive licenses for public interest reasons, was broad enough to incorporate the amendment.[225] This does not seem to be the case for Kenya as section 75(2)(b) is rigid, requiring a compulsory license to be used primarily to satisfy domestic needs as a rule.[226]

The author recommends that the Kenyan parliament create implementing legislation to provide for Article 31*bis*. The legislation ought to amend section 75(2)(b) of the Industrial Property Act, as it adopts the 'predominant-domestic-supply' rule. Perhaps the amendment can create exceptions to this rule, such that it allows the requirement to be waived when the system if Article 31*bis* is invoked. By adopting a model similar to Botswana's Industrial Property Act, Kenya could position itself as *both* a pharmaceutical importer and exporter, maximising benefits within the EAC. Such an approach would unlock Kenya's potential as a regional pharmaceutical leader and significantly enhance accessibility of medicines across the EAC. This dual role would ensure that Kenya not only meets its domestic needs but also supports neighbouring countries by providing pharmaceuticals, thereby bolstering regional health security.

## VI. Conclusion

This paper has evaluated the significance of compulsory licences under Article 31*bis* in improving access to medicines in the EAC. Regional collaboration in the use of such licenses is particularly advantageous for developing EAC members, as it consolidates smaller markets into a larger one, attracting suppliers and bolstering negotiation power.

Nevertheless, the absence of legislation implementing Article 31*bis* into domestic law hampers members' ability to fully utilize the system. This is because the absence of such legislation (i) prevents them from relying on the system either as an importer or as an exporter when in need of pharmaceutical products, (ii) leaves the member with the option of using the compulsory license under

[224] Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation', 7.

[225] World Trade Organisation, 'Members' law implementing the 'Paragraph 6' system' -<https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm> on 28 November 2023.

[226] Section 75(2) (b), *Industrial Property Act* (Act No 3 of 2001).

Article 31 alongside the provision's obstacles (including the limited number of suppliers able and willing to meet the requirements on supply) and (iii) hinders the ability of RTAs under Article 31*bis* (3) to fully take advantage of the compulsory licensing system by utilising it collectively.

The analysis focuses on Kenya's potential within regional efforts aligned with the Article 31*bis* framework, highlighting its substantial pharmaceutical capacity and potential as a manufacturing hub. Therefore, Kenya's lack of implementing legislation incorporating Article 31*bis* into its Industrial Property Act obstructs regional cooperation by both limiting Kenya's capacity to export pharmaceuticals to fellow EAC states and hindering the combination of the power of the markets of EAC states.