COMPULSORY LICENSING FOR PHARMACEUTICAL ACCESS IN EAST AFRICA: THE CHALLENGE OF KENYA'S FAILURE TO ADOPT ARTICLE 31*BIS* OF THE TRIPS AGREEMENT

Submitted in partial fulfilment of the requirements of the Bachelor of Laws Degree,
Strathmore University Law School

By

Vicky Kinya Miriti

134612

Prepared under the supervision of

Ms. Janet Njambi Macharia

March 2024

Word count:16708

TABLE OF CONTENTS

ACKNOWLEDGEMENTS

The completion of this dissertation would not have been possible without the support I received from my supervisor, Ms. Janet Njambi and my friends and family. As a result, I would like to express my gratitude to Ms. Janet Njambi for her detailed feedback, encouragement, and guidance. Since the very beginning of the research process, she has helped me assess and critique my ideas and how I put them across. The many back-and-forth sessions have been invaluable to my writing and more importantly, my thinking. I would like to especially thank her for introducing me to the world of International Trade Law through the John H. Jackson Moot Court Competition, without which this dissertation may never have been written.

I would also like to appreciate the words of encouragement and consistent check-ins from both friends and family. Through their constant support I was able to push forward, especially in the final stretch of the research and writing process. Their concern, practical tips and suggestions greatly contributed to my mental clarity and peace of mind while tackling each chapter. I am eternally grateful for their assistance.

DECLARATION

I, **VICKY KINYA MIRITI,** do hereby declare that this research is my original work and that to the best of my knowledge and belief, it has not been previously, in its entirety or in part, been submitted to any other university for a degree or diploma. Other works cited or referred to are accordingly acknowledged.

Signed: ——————————————

Date: **18/03/2024**

This dissertation has been submitted for examination with my approval as University Supervisor.

Signed: ——————————————

MS. JANET NJAMBI MACHARIA

ABSTRACT

Sub-Saharan Africa, including East Africa, grapples with profound public health challenges exacerbated by limited access to pharmaceuticals. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, enacted in 1995, introduced patent rights for pharmaceutical products, restricting generic production. Article 31 of the TRIPS Agreement permits compulsory licensing to facilitate cheaper generic versions and its amendment, Article 31*bis,* enables countries in a regional trade area to combine their markets and thus incentivise manufacturers to supply them with the needed medicines. However, the implementation of the Article 31*bis* system, intended to enhance access, remains underutilized with many smaller economies lacking legislation adopting the amendment into law.

Kenya's stringent patent regime, compounded by its lack of legislation implementing Article 31*bis,* stifles regional cooperation within the East African Community (EAC). Kenya, boasting the largest pharmaceutical market and sector in the EAC, is therefore prevented from leverage the Article 31*bis* system, impeding regional efforts to increase economies of scale and alleviate pharmaceutical accessibility issues. Urgent action is needed to adopt implementing legislation and unlock the potential benefits of compulsory licensing, facilitating broader regional collaboration and addressing medication access challenges in the EAC.

LIST OF ABBREVIATIONS

AfCFTA – African Continental Free Trade Area

APIs - Active Pharmaceutical Ingredients

ARVs - Antiretroviral drugs

Doha Declaration - Doha Declaration on the TRIPS and Public Health

DRC - Democratic Republic of Congo

EAC - East African Community

EAC Treaty - Treaty for the Establishment of the East African Community

GATT - General Agreement on Tariffs and Trade

IP - Intellectual Property

IPA - Industrial Property Act

IPR – Intellectual Property Protection

LDC – Least Developed Country

ROs - Research Objectives

RPSC - Regional Pharmaceutical Supply Centre

RTA - Regional Trade Agreement

TB - Tuberculosis

TRIPS - Agreement on the Trade-Related Aspects of Intellectual Property Rights

VCLT - Vienna Convention on the Law of Treaties

WTO - World Trade Organisation

WTO Agreement - Agreement Establishing the World Trade Organization

LIST OF CASES

Australia - Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, DS467, WTO Panel Report, 2013.

China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights, DS362, WTO Panel Report, 2009.

European Communities — Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, DS174, WTO Panel Report, 2006.

European Communities and its Member States — Tariff Treatment of Certain Information Technology Products, DS375, 2011.

Japan — Taxes on Alcoholic Beverages, DS8, 1998.

United States — Import Prohibition of Certain Shrimp and Shrimp Products, DS58, 2001.

United States — Standards for Reformulated and Conventional Gasoline, DS2, 1997.

LIST OF LEGAL INSTRUMENTS

Agreement Establishing the World Trade Organization

Agreement on the Trade-Related Aspects of Intellectual Property Rights

General Agreement on Tariffs and Trade

Treaty for the Establishment of the East African Community

Understanding on the Rules and Procedures Governing the Settlement of Disputes

Vienna Convention on the Law of Treaties

CHAPTER ONE

INTRODUCTION

1.1 Background

Sub-Saharan Africa, including East Africa,[1] experiences the most severe impact of disease on a global scale.[2] In fact, the 'gravity' of the public health problems experienced by Africa generally is recognised multi-nationally.[3] Following the 1995 Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),[4] pharmaceutical products became recognised for patenting.[5] This grants patent-holders monopoly rights over the manufacture, use, offer for sale, sale and importation of their pharmaceutical inventions.[6] The seven countries of the East African Community (EAC)[7] are party to the TRIPS Agreement by virtue of their membership in the World Trade Organisation.[8] This means that producing generic versions of the products to increase accessibility in the EAC was, as a general rule, prohibited.

To enable further access to pharmaceutical products, the TRIPS Agreement also provides for the compulsory license exception. This exception is provided for in Article 31, allowing a Member to authorize the production of generic pharmaceutical products without authorization from a patent holder.[9] This flexibility is meant to enable the production of cheaper versions of patented pharmaceuticals.[10]

---

[1] https://www.newworldencyclopedia.org/entry/Sub-Saharan_Africa on 19th October 2023.
[2] Roser M, Ritchie H and Spooner F, 'Burden of Disease' Our World In Data, September 2021 - https://ourworldindata.org/burden-of-disease on 6 October 2023.
[3] World Trade Organization, Ministerial Declaration of 20 November 2001, WT/MIN (01)/DEC/2 (2002).
[4] Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299.
[5] Article 27 (1), Agreement on Trade-Related Aspects of Intellectual Property Rights.
[6] Article 28, Agreement on Trade-Related Aspects of Intellectual Property Rights.
[7] East African Community on 3 January 2023.
[8] 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.
[9] Article 31, Agreement on Trade-Related Aspects of Intellectual Property Rights.
[10] Niesporek A, 'Compulsory licensing of pharmaceutical products & access to essential medicines in developing countries,' BMOS Thesis, Linköping University, Sweden, 2005, 26.

However, the Article 31*bis* system is not utilised much with some describing the system as 'stagnated.'[11] Igobkwe and Tosatso, while reviewing scholarship and the work of international intellectual property organisations, categorise the reasons offered for such stagnation into four broad groups.[12] They are governmental and corporate interferences, obtrusions caused by domestic laws and free trade agreements, procedural complexities, and economic challenges.[13]

After detailing why the three other explanations may not be viable, Igobkwe and Tosatsu explain that the economic challenges faced in the local production and purchase of pharmaceuticals is the main hindrance to the use of the Article 31*bis* system.[14] This is because the various costs associated with production or purchase; such as the large investment required upfront, the limited likelihood of profitability due to small markets in the developing world and the extreme vulnerability to patentees lowering their own prices, make it difficult for economies of scale, which lower the cost of production, to be achieved.[15]

To harness economies of scale for increased purchasing power and local production, paragraph 3 of the Article 31*bis* amendment provides for certain cooperation between members of a Regional Trade Agreement (RTAs). It waives the requirement in Article 31 (f) of the TRIPS Agreement which conditioned the use of a compulsory license on the predominant supply to the relevant domestic market. This waiver applies to RTAs where at least half of its membership is composed of Least Developed Countries (LDCs). The implication is that an exporting country within such an RTA would be able to export 100% of the pharmaceuticals under a compulsory license. In comparison, the Article 31 (f) system which requires 'predominant' domestic supply implies the burden to produce the products majorly for the

[11] Igbokwe and Tosato, 'Access To Medicines and Pharmaceutical Patents: Fulfilling The Promise of TRIPS Article 31*BIS*,' Faculty Scholarship at Penn Carey Law, Pennsylvania, 2022, 57.
[12]Igbokwe and Tosato, 'Access To Medicines and Pharmaceutical Patents: Fulfilling The Promise of TRIPS Article 31*BIS*,' 58.
[13] Igbokwe and Tosato, 'Access To Medicines and Pharmaceutical Patents: Fulfilling The Promise of TRIPS Article 31*BIS*,' 58.
[14] Igbokwe and Tosato, 'Access To Medicines and Pharmaceutical Patents: Fulfilling The Promise of TRIPS Article 31*BIS*,' 69-72.
[15] Igbokwe and Tosato, 'Access To Medicines and Pharmaceutical Patents: Fulfilling The Promise of TRIPS Article 31*BIS*,' 69-72.

domestic market.[16] This would require at least 50% production for domestic use when exporting to another country and, at least 40% for a country exporting to three trading partners.[17]

The EAC is recognized as an RTA by the WTO[18] and all its Members have formally recognised the Article 31*bis* amendment.[19] Despite this, none of them have created implementing legislation to harness the benefits of Article 31*bis*.[20] Especially damning is Kenya's compulsory licensing regime. In addition to lacking implementing legislation adopting Article 31*bis*, section 75(2)(b) of Kenya's Industrial Property Act (IPA), makes the predominant domestic supply rule in Article 31 (f) mandatory with no exception. This prevents it from utilising the Article 31*bis* waiver and the regional initiative in Article 31*bis* 3.

Kenya has one of the largest pharmaceutical markets in the EAC, it leads the region in exporting pharmaceuticals, especially with other East African countries as its main importers,[21] and boasts the largest pharmaceutical sector in the EAC.[22] As a result, its inability to use the Article 31*bis* system prevents the EAC from combining its states to form as large a market as possible to increase economies of scale. In addition, Kenya's system also hinders it from serving as an alternative supplier of generic pharmaceuticals which would ease the regions importation under Article 31*bis* 3. As such Kenya's IPA in addition to its failure to implement adopting legislation for Article 31*bis* wastes the potential that Kenya could otherwise bring to the EAC.

---

[16]Intellectual Property Rights Commission, WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries, 14 February 2002, 17.
[17]Intellectual Property Rights Commission, WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries, 14 February 2002, 17.
[18] https://rtais.wto.org/UI/PublicSearchByMemberResult.aspx?membercode=404 on 3 January 2023.
[19] https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm on 19th October 2023.
[20]Article 31*BIS* of TRIPS: How can African countries benefit from this amendment?, Lexology on 9 June 2017 <https://www.lexology.com/library/detail.aspx?g=df73ba15-2a55-4337-86ed-756d2ba67e8b > on 19th October 2023.
[21] The East African Community, 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027, 2017, 17.
[22] The East African Community, 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027, 2017,16.

1.2 Statement Of The Problem

Section 75(2)(b) mandates Kenya to produce or import at least 50%[23] of the pharmaceuticals *for use within Kenya*, while intending to export or re-export to other East African countries under a compulsory license. As Kenya has not adopted implementing legislation to Article 31*bis* to enable the export or re-export of up to 100% of the products within the EAC, it is unable to exploit compulsory licenses fully to enable access to pharmaceuticals in the region. Further, it is unable to band together with other EAC Partner States under Article 31*bis* 3 to increase the market size of the region and thus incentivise foreign suppliers to supply to the region. The lack of lack of implementing legislation in Kenya combined with the rigidity of section 75(2)(b) of the IPA is therefore the focus of the study, considering the benefits the EAC would otherwise enjoy.

1.3 Research Objectives

1. To assess the value of a compulsory license under Article 31*bis* in achieving access to medicines in the EAC RTA.
2. To examine the place of domestic implementing legislation in compulsory licensing under Article 31*bis* of the TRIPS Agreement.
3. To assess Kenya's contribution to the regional approach in article 31*bis* 3 and thus the gains foregone by the EAC due to its lack of implementing legislation

1.4 Research Questions

1. What is the value of a compulsory license under Article 31bis in achieving access to medicines in the EAC RTA?
2. What is the place of domestic implementing legislation in compulsory licensing under Article 31bis of the TRIPS Agreement?
3.

[23]Or 40% as discussed while defining 'predominantly.'

a. What contribution could Kenya make to the use of a regional compulsory license in the EAC?
b. What is the impact of the lack of implementing legislation to this contribution?

1.5 Hypothesis

Kenya's failure to enact implementing legislation for Article 31*bis*, along with the inflexibility of section 75(2)(b) of its Industrial Property Act, hampers the East African Community (EAC) from effectively utilizing the regional mechanism outlined in Article 31*bis* 3. This legal gap prevents the EAC from fully integrating its markets to attract suppliers, while also hindering Kenya from leveraging its growing local production capacities as a supplier within the regional mechanism. Consequently, Kenya's legislative shortcomings impede efforts to improve medicine accessibility in the EAC.

1.6 Justification

As pointed out in the literature review, most scholarly work dealing with the problem stops short of a discussion on why it is particularly bad, especially for the EAC at large. This study is justified, firstly, because it presents the wider scope of the problem; clearly identifying the butterfly effect of a single provision of a single country's law where it provides for no exceptions. This study is therefore relevant in answering the question 'so what?' put to those who state that 75(2)(b) is inconsistent with Article 31*bis*.

Further, this study is useful in so far as we are interested, and we are, in the effective functioning of the EAC for the benefit of its constituent states. One recent objective of the EAC is its goal to assist East African nations to utilise TRIPS flexibilities.[24] Compulsory licensing is one such flexibility. Therefore, by delving into Kenya's ability to make strides in this goal and a potential cap to this ability, this study is worth the paper it is written on. In addition, as pointed out in the literature review, the compulsory licensing system may very

[24] The East African Community, EAC Regional Intellectual Property Policy on the utilization of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation, February 2013.

well not be used. However, the EAC will be shown to still be able to benefit so long as Kenya's compulsory licensing regime allows it to take advantage of the Article 31*bis* waiver of predominant domestic use. Such an analysis is therefore beneficial in practice.

Finally, the study is also relevant considering recent events. In March 2020, the novel coronavirus spread worldwide with the World Health Organisation declaring it to be a pandemic.[25] Inequitable access characterised the distribution of the vaccines created to help combat the pandemic, with vaccines mainly moving between developed countries. As such, the WHO recognised the role of global vaccination in curbing the pandemic. It recognised; *the role of extensive immunisation against COVID-19 as a global public good for health in preventing, containing and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available.*[26] Given the outcry to prevent continuous inequitable access in essential services, this study is useful in pointing out how to maximise a flexibility to promote further access.

1.7 Conceptual Framework

This study is founded on the access to medicines campaign considering the impact of intellectual property (IP) protection, particularly the TRIPS Agreement, on public health. As earlier mentioned, sub-Saharan Africa suffers from one of the highest disease burdens worldwide.[27] 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.[28] Some chose to weaken patent protection specifically for pharmaceuticals,[29] others chose to use

[25] WHO, Seventy Third Health Assembly, Agenda Item 3, COVID-19 Response, WHA 73.1 19 May 2020.
[26] WHO, Seventy Third Health Assembly, Agenda Item 3, COVID-19 Response, WHA 73.1 19 May 2020.

[27] Roser M, Ritchie H and Spooner F, 'Burden of Disease' Our World In Data, September 2021 - https://ourworldindata.org/burden-of-disease on 6 October 2023.
[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' 10 *Journal of International Economic Law* 4, 2007, 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.

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]

The full effects of TRIPS implementation were felt following the end of the transition periods allowed to developing country Members by Article 66 (1) of the TRIPS Agreement.[33] Developing countries combating serious health issues were obliged to enforce the patent rights and protections of pharmaceutical companies in their territories.[34] As a result, the freedom governments had to act amid public health crises was severely limited. 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.[35] This thus brought an end to governments' ability to discriminate between different industries in patent protection for purposes of enabling access to inexpensive medication.

The WTO was forced to reckon with the impact of TRIPS implementation on public health in the late 1990s and early 2000s especially due to the devastating and global impact of the HIV/AIDS epidemic.[36] As countries sought to provide their citizens with cheaper generics, they were met with retaliation from pharmaceutical companies who aimed to prevent generic production in Brazil and Thailand.[37]

---

[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] Article 66 (1), Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[34] Article 1 (1), Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[35] Article 27, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[36] Oxfam Briefing Paper 95, Patents versus patients five years after the Doha Declaration, 2006, 5.
[37] Oxfam Briefing Paper 95, Patents versus patients five years after the Doha Declaration, 2006, 5.

Zimbabwe, on behalf of the African Group, at a special meeting of the TRIPS Council highlighted the global inequalities in access to antiretroviral drugs (ARVs).[38] 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.[39] 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.[40] Eventually, the result was the creation of the Doha Declaration on the TRIPS and Public Health ('Doha Declaration') of November 2001 where all WTO Members agreed that the TRIPS Agreement does not and should not prevent any Member form taking measures to protect public health.[41]

1.8 Literature Review

1.8.1 On the promise of Article 31 *bis*

Before the Article 31*bis* Amendment, Article 31 was the relevant TRIPS provision on compulsory licensing. Like Article 5A of the Paris Convention, a predecessor of the TRIPS, Article 31 prevents the misuse of the system by laying out conditions for using the system.[42] The conditions act as safeguards. But even with the apparent balance between public health and patent protection something was amiss. The requirements of the conditions made it ineffective for developing countries as the predominant domestic use requirement prevented their importation of adequate quantities of the vaccines. Enters the Article 31*bis* amendment.

---

[38] 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.
[39] 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.
[40] 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.
[41] World Trade Organisation Ministerial Conference, *Declaration on the TRIPS Agreement and public health*, WT/MIN (01)/DEC/2, 20 November 2001, Paragraph 4.
[42] Taubman, Wager and Watal (eds), A handbook on the WTO TRIPS Agreement, Cambridge University Press, Cambridge, 2020, 120.

It was to respond to the problem faced by countries lacking sufficient or any manufacturing capacity,[43] allowing them to import adequate quantities without the shackles of predominant domestic use requirements.

Some have praised the system. While recognising that the system has been used a total of 1 time under the paragraph 6 system[44] and not much since then, it has been argued that the limited use of Art 31*bis* is attributable to its nature as only one part of a larger system to promote access to pharmaceuticals.[45]

Scholars like Vincent have disputed this argument, stating that for such an idea to hold up, other means must exist that enhance access to medicines. He gives the examples of a Medical Patent Pool and different pricing models in the developing world, but states that these too are unfeasible because they presume the availability of manufacturing capacity.[46]

Vincent himself posits another potential argument for 31*bis*, that it is ahead of its time *because* the only time it was used, it functioned as expected.[47] He criticised such a positive account, because it doesn't consider data showing the decreased issuance of compulsory licenses since 2006.[48]

Others have proposed alternatives to the 31*bis* system, for instance, arguing that the increase under patent terms will lead to more access.[49] Although this idea has been looked at with

[43] Taubman, Wager and Watal (eds), A handbook on the WTO TRIPS Agreement, Cambridge University Press, Cambridge, 2020, 120. See also World Trade Organization, Decision of the General Council of 30 August 2003, WT/L/540 and Corr.1 (2003), para 11.
[44] This took place in 2006 by Rwanda who imported from Canada.
[45] Promoting access to medical technologies and innovation, WIPO, https://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf,178.
[46] Vincent N, 'Trip-ing up: the failure of trips article 31*BIS*' *24 Gonzaga Journal of International Law 1*, 2020, 30-32.
[47] [47] Vincent N, 'Trip-ing up: the failure of trips article 31*BIS*' 32.
[48] Reed B & Randall K, Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis, 9 Plos Medicine1, 2012, 7.
[49] Vincent N, 'Trip-ing up: the failure of trips article 31*BIS*' *24 Gonzaga Journal of International Law 1*, 2020, 31.

caution,[50] there are claims surrounding the argument that may make it easier to see the reasoning of those with this perspective. For instance, Mercurio, who has represented developing countries in negotiations at the WTO, has spoken on the impact of having less patent protection i.e., through a waiver of patent rights.[51] Mercurio stated that a waiver of patent rights may restrict the number of raw materials available to companies better equipped to produce better quality vaccines because all companies would be authorised to use them. Although arguments like Mercurio's do not directly defend increasing patent protection, they certainly lend credibility to the existence of patent protection even within a compulsory license framework.

Developing countries have also proposed that the 31*bis* system creates too many barriers, both administratively and legally, to function effectively in crisis situations such as the COVID-19 pandemic.[52] It seems like the Article 31*bis* system has not been painted in the best of lights.

1.8.2 On Article 31*bis* and EAC

Perhaps the closest discussion of the contribution of Article 31*bis* to RTAs like the EAC was done by the East African Community in its policy covering intellectual property in the region and the utilization of public-health-related TRIPS-flexibilities.[53] In its discussion, the EAC Sectoral Council on Regional Cooperation on Health mentioned the need for state parties to amend their national legislation to allow the export of up to 100% of their pharmaceuticals to their EAC counterparts.[54] While it also discusses the status of the EAC as an LDC-dominated

[50] See for instance, Vincent N, 'Trip-ing up: the failure of trips article 31*BIS*' *24 Gonzaga Journal of International Law 1*, 2020, 31, where the author questions the correctness of increasing patent protection in developing countries.
[51] Webinar on necessity or flexibility: reflections on the negotiations for a TRIPS waiver for vaccines, https://www.youtube.com/watch?v=6pjtJJ1kvLA on 5 August 2022.
[52] World Trade Organization, Waiver from certain provisions of the TRIPS agreement for the prevention, containment, and treatment of covid-19 communication from India and South Africa, IP/C/W/669.
[53] The East African Community, EAC Regional Intellectual Property Policy on the utilization of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation, February 2013.
[54] The East African Community, EAC Regional Intellectual Property Policy on the utilization of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation, February 2013, 19.

trade agreement,[55] it does not delve into the unique position *Kenya* is in to utilize Article 31*bis*, whether in manufacturing or re-exportation and therefore, the extent of the hindrance section 75(2)(b) has.

Although other scholarly work has not explicitly made this link, it has been recognised that regional trade agreements could help developing countries maximise the 31*bis* system. This is because they allow countries to share the administrative and financial costs of the system between them.[56]

1.8.3 On the problem of Section 75(2)(b) and the lack of implementing legislation

Although there is existing scholarly work on the topic, many researchers have simply identified the problem posed by Section 75(2)(b) without discussing the leverage the EAC would have should Kenya amend this provision. Further, they do not spend much time on the impact of the lack of implementing legislation to Article 31*bis* in Kenya.

Ogendi, in his thesis, identifies the predominant domestic use requirement under section 75(2)(b) to be the 'most controversial requirement' in need of 'urgent reform' to align with the developments of the TRIPS Agreement.[57] Nyaga, in a footnote, mentions that the mirroring of Article 31(f) in Section 75(2)(b) prevents Kenya from fully utilising the compulsory license as further developed by the Paragraph 6 Decision.[58] Another example is Baker who, while discussing the proposed Intellectual Property Bill of 2020 to consolidate intellectual property law in Kenya, proposed that Kenya should amend its intellectual property law to comply with

---

[55] The East African Community, EAC Regional Intellectual Property Policy on the utilization of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation, February 2013, 19.
[56] Vincent N, 'Trip-ing up: the failure of trips article 31*BIS*' *24 Gonzaga Journal of International Law 1*, 2020, 33.
[57] Ogendi P, 'Access to essential medicines and the utilization of compulsory licensing and parallel importation in Kenya and South Africa' unpublished thesis, University of Nairobi, Nairobi, 2011, 46.
[58] Nyaga J, 'Implementing parallel importation and licensing mechanisms to increase access to medicines in Kenya,' unpublished LLM Thesis, Stanford University, California, 2009, 39.

the waiver of Article 31(f) contained in Article 31*bis* of the TRIPS Agreement.[59] Like Ogendi, his discussion presents the paradox of 31(f) providing a system for increasing access to medication but locking out those who most need it (developing and least developed countries) by restricting importation under a compulsory license. Baker does not delve into a discussion on the East African region and the impacts Kenya's amendment would serve to it. The trend is repeated by additional scholars writing about Kenya,[60] and the developing world at large.[61]

1.9 Methodology

This study is primarily conducted using qualitative research, relying mainly on secondary sources such as books, journal articles, and reports detailing the existence of various claims made. Throughout the study, primary sources are also utilized when setting out the law, including the provisions of the WTO Agreement, the TRIPS Agreement, and Kenya's Industrial Property Act. Furthermore, reference is made to relevant treaties and policy documents of the EAC and the AfCFTA where applicable.

In the first part of this study on the value of a compulsory license in the EAC, a historical analysis is utilized to go over the developments in the accessibility of pharmaceuticals before and after they became patentable. Secondary resources are useful in this process, helping reveal the factual situation. Reference will also be made to several other countries to buttress

[59]Baker B, 'Kenya's intellectual property bill, 2020, and its shortcomings in adopting all lawful TRIPs public health flexibilities' PIJIP/TLS, Research Paper Series Number 53, June 2020, "Kenya's Intellectual Property Bill, 2020, and Its Shortcomings in Adop" by Brook K. Baker on 31 December 2022, 16.

[60]See Health Systems Resource Centre, Willingness, and ability to use TRIPs flexibilities: Kenya case study, September 2004, 26.

[61] See Wartini S, 'The legal implication of compulsory license pharmaceutical products in the TRIPS Agreement to the Protection of the right to health in developing countries,' 18 *Jurnal Dinamika Hukum* 1, 2018, 6 who sites manufacturing capacity as a reason why the developing world would be unable to make use of the system under Article 31(f). Also, see Vincent N, 'Trip-ing up: the failure of trips article 31*BIS*' *24 Gonzaga Journal of International Law 1*, 2020, 9-11. Vincent gives a historical overview of the generic pharmaceutical sector before the birth of the TRIPS Agreement. He shows that pre-TRIPS, countries that did not offer patent protection to pharmaceuticals were able to produce generic products and sell them for much cheaper than their branded counterparts in other countries that did not patent the products. The TRIPS Agreement provided for the patentability of pharmaceuticals and required its Members to provide such protection. Vincent argues that this affected the customers of generic-product-producing countries the hardest as the producing countries were bound to manufacture mostly for domestic use.

the points on the shift in the accessibility of pharmaceuticals in the EAC. Additionally, while discussing the practical contribution of compulsory licenses, information is drawn from experts in the field. This is in furtherance of the broader claim made in this section; that compulsory licenses are beneficial in various ways to the EAC.

The second section of this study deals with the value of domestic legislation to TRIPS implementation. It reviews WTO law and jurisprudence as well as scholarly work to establish the importance of domestic legislation to utilize Article 31bis. The different primary sources are especially relevant here to expound on how the system is to operate. Furthermore, scholars, academics, and resource pages of the relevant international organizations are also heavily cited.

The third section of this study tackles Kenya's contribution to the use of compulsory licenses in the regional mechanism under Article 31bis. Similarly, it focuses on secondary sources where Kenya is the subject of study, tracking Kenya's usefulness in the pharmaceutical industry. Together, the evidence is linked to prove Kenya's value to the EAC specifically where a regional compulsory license is relevant.

1.10 Chapter Breakdown

This chapter serves as the introductory segment of the study, delineating the identified problem and presenting an overview. It articulates the study's hypothesis and theoretical framework. Subsequent chapters will methodically explore the research objectives while addressing the posed questions.

Chapter two delves into the practical impact of compulsory licenses within the East African Community, with a particular emphasis on pharmaceutical access. It elucidates the necessity for the exception in Article 31 and its subsequent extension in Article 31*bis*, highlighting the enhanced accessibility afforded by the 31*bis* amendment, especially to developing nations lacking vaccine manufacturing capabilities. This chapter aims to underscore the potential benefits the EAC could accrue by embracing the 31*bis* system as a Regional Trade Area.

In chapter three, the envisioned implementation of Article 31*bis* of the TRIPS Agreement by WTO Members is outlined. It elucidates the significance of domestic legislation in leveraging the waiver in Article 31*bis*, underscoring the ramifications of its absence.

Chapter four substantiates the hypothesis, demonstrating how the existing paradigm, shaped by Section 75(2)(b) of the IPA and the absence of implementing legislation for Article 31*bis*, restricts the benefits of the compulsory licensing system. It delves into Kenya's overall development and its pharmaceutical sector to showcase its potential contribution to the regional initiative under Article 31*bis* and the consequential losses to the EAC.

Lastly, chapter five offers recommendations aimed at mitigating the identified issues, thereby enabling Kenya to play a pivotal role in bolstering the EAC's advantages in using the 31*bis* system.

CHAPTER TWO

ASSESSING THE VALUE OF A COMPULSORY LICENSE UNDER ARTICLE 31*BIS* IN ACHIEVING ACCESS TO MEDICINES IN THE EAST AFRICAN COMMUNITY REGIONAL TRADE AGREEMENT

2.1 Introduction

The East African Community (EAC) is a regional intergovernmental organization composed of eight states from East Africa.[62] These states are Kenya, Tanzania, Uganda, Rwanda, the Democratic Republic of Congo, Somalia, Burundi and South Sudan.[63] It was established following the entry into force of the Treaty for the Establishment of the East African Community on 7th July 2000[64] to create policies and programs for cooperation on various fields including political, social and cultural, for the mutual benefit of the Partner States.[65]

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*, regional trade agreements (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.[66] Importantly, it leverages their regional status to allow their member countries to issue compulsory licenses to import and produce pharmaceuticals and then freely re-export them to their fellow members who need them.[67] As such, it provides a collaborative approach to addressing similar health needs within a particular region.

---

[62] -<https://www.eac.int/overview-of-eac>- Accessed on 28 December 2023.
[63] -<https://www.eac.int/overview-of-eac>- Accessed on 28 December 2023.
[64] -<https://www.eac.int/eac-history>- Accessed on 28 December 2023. Also see Article 2, *Treaty for the Establishment of the East African Community*, 7 July 2000.
[65] Article 5 (1), Treaty for the Establishment of the East African Community, 7 July 2000.
[66] Article 31bis, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[67] Article 31bis, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.

In the following sections, this chapter addresses the main objective which is to examine the importance of a compulsory license using the framework in Article 31*bis* 3 to the EAC RTA. It will do so in two broad sections which will be further subdivided. The first offers a history of the access to medicines campaign aiming to help the reader understand the intersection of intellectual property law under the TRIPS regime and public health.

The second section discusses the regional mechanism under Article 31*bis* 3 tracing the failure of single-state action, and justifying regional cooperation. This section also addresses proposed tools such as pooled procurement and regional pharmaceutical centres which, used together with the 31*bis* strategy, appear promising to promote the access of medicines. Overall, the second section attempts to highlight the benefits the EAC would gain from adopting the 31*bis* strategy in combination with the proposals. This chapter concludes by offering a summary of the conclusions drawn while conducting the assessment of the value of a compulsory license to the EAC RTA.

2.2 A brief history of access to medicines and the TRIPS regime

2.2.1 Access to medicines before the TRIPS Agreement

A wide range of diseases have afflicted the developing world. These include the HIV/AIDS pandemic, tuberculosis (TB), malaria, acute respiratory infections and sexually transmitted diseases.[68] 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.[69] This is because the previous international intellectual property rules were not quite as demanding of countries.[70] For instance, the Paris Convention for the Protection of Industrial Property of 1883, spoke to rules of priority and national treatment, leaving governments the right to

[68] Médecins Sans Frontières Briefing for the 5th WTO Ministerial Conference, *Doha Derailed: A Progress Report on TRIPS and Access to Medicines*, 2003, 6.
[69] 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 *Journal of International Economic Law* 4, 2007, 927.
[70] 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.

formulate patent systems.[71] Some chose to weaken patent protection specifically for pharmaceuticals,[72] others chose to use compulsory licensing to override exclusive patent rights[73] and some even denied patent protection over pharmaceuticals altogether.[74] These efforts encouraged competition between big pharmaceutical companies and their cheaper generic versions allowing poor countries to have access to affordable medicines.[75]

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 some key deciding factors in the accessibility of medicines in the developing world. [76]

2.2.2 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.[77] As part of the package prospective members of the World Trade Organisation (WTO) had to accept, the Members were obliged to afford intellectual property protection, extending even to pharmaceutical goods.[78] The full effects of TRIPS implementation were felt following the end of the transition periods allowed to developing country Members by Article 66 (1) of the TRIPS Agreement.[79] As such, developing countries combating serious health issues were

[71] 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.
[72] 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.
[73] Anderson H, 'We can work it out: co-op compulsory licensing as the way forward in improving access to anti-retroviral drugs,' 175.
[74] Anderson H, 'We can work it out: co-op compulsory licensing as the way forward in improving access to anti-retroviral drugs,' 174.
[75] 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.
[76] 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
[77] Oxfam Briefing Paper 95, Patents versus patients five years after the Doha Declaration, 2006, 5.
[78] Oxfam Briefing Paper 95, Patents versus patients five years after the Doha Declaration, 2006, 5.
[79] Article 66 (1), Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.

obliged to enforce the patent rights and protections of pharmaceutical companies in their territories.[80]

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.[81] 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.[82] These are considered the 'exclusive rights' of the patent holder.[83] This provision would grant monopoly power to pharmaceutical companies by enabling them to essentially kill competition from cheaper generics as 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.[84] This enabled pharmaceutical companies to sell using a 'low volume, high margin' strategy that would allow them to reap the most profit.[85] This, of course, was problematic to the world's poor who could not afford life-saving medication.[86]

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

---

[80] Article 1 (1), Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[81] Article 27, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[82] Article 28, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[83] See the title of Article 28.
[84] Article 28, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[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,' 970.
[86] Oxfam Briefing Paper 95, Patents versus patients five years after the Doha Declaration, 2006.

unreasonably prejudice the legitimate interests of the patent owner." Article 31 would also confine the use of a compulsory license by creating requirements such as prior negotiation with a patent holder and the limitation of the scope and duration of the license and the notorious predominant-domestic use requirement that is the subject of this paper.[87]

2.2.3 Access to medicines leading up to the Doha Rounds of Negotiation

The World Health Organisation and not the WTO, an international trade organisation, is the primary institution responsible for addressing the public health needs of developing countries.[88] However, the WTO did become 'a central focus' due to its development of rules governing patents while neglecting to consider the implications of this on the health sector.[89]

The WTO was forced to reckon with the impact of TRIPS implementation on public health in the late 1990s and early 2000s especially due to the devastating and global impact of the HIV/AIDS epidemic.[90] As countries sought to provide their citizens with cheaper generics, they were met with retaliation from pharmaceutical companies who aimed to prevent generic production in Brazil and Thailand.[91]

Zimbabwe, on behalf of the African Group, at a special meeting of the TRIPS Council highlighted the global inequalities in access to antiretroviral drugs (ARVs).[92] 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.[93] The African Group stated that the Members needed to clarify the room

---

[87] Anderson H, 'We can work it out: co-op compulsory licensing as the way forward in improving access to anti-retroviral drugs,' 175.
[88] 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.
[89] Abbott F, 'The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO,'505.
[90] Oxfam Briefing Paper 95, Patents versus patients five years after the Doha Declaration, 2006, 5.
[91] Oxfam Briefing Paper 95, Patents versus patients five years after the Doha Declaration, 2006, 5.
[92] 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.
[93] 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.

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.[94] Eventually, the result was the creation of the Doha Declaration on the TRIPS and Public Health ('Doha Declaration') of November 2001 where all WTO Members agreed that the TRIPS Agreement does not and should not prevent any Member form taking measures to protect public health.[95] Further, it reaffirmed a Member's right to " *use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose* [public health, specifically access to medicines for all]."[96]

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.[97] In paragraph 6 it tasked the TRIPS Council with finding an expeditious solution and reporting it to the General Council.[98]

2.2.4 Access to medicines following the Doha Declaration on TRIPS and Public Health

The solution that was eventually adopted is commonly known as the 'Paragraph 6 System" in reference to its roots in the Doha Declaration.[99] It waived the obligation in Article 31 (f) for pharmaceuticals and thus eased the use of compulsory licenses for their export, allowing up to

[94] 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.
[95] World Trade Organisation Ministerial Conference, *Declaration on the TRIPS Agreement and public health*, WT/MIN (01)/DEC/2, 20 November 2001, Paragraph 4.
[96] World Trade Organisation Ministerial Conference, *Declaration on the TRIPS Agreement and public health*, WT/MIN (01)/DEC/2, 20 November 2001, Paragraph 4.
[97] < https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm >- Accessed on 3 January 2024.
[98] World Trade Organisation Ministerial Conference, *Declaration on the TRIPS Agreement and public health*, WT/MIN (01)/DEC/2, 20 November 2001, Paragraph 6.
[99] < https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm >- Accessed on 3 January 2024.

100% of their export.[100] However, it was not easily come by. During negotiations, Members were split over three key issues: the scope of diseases, eligible countries, and the TRIPS articles to be addressed.[101]

The governments of major pharmaceutical companies such as the United States, lobbied to restrict the scope of diseases.[102] They argued that (i) the Doha Declaration limited the scope by making reference the specific ailments of HIV/AIDS, tuberculosis and malaria,[103] (ii) that from an investment perspective, it is important to restrict the goods for which a compulsory license can be obtained over as such licenses may discourage investment into research and development (R&D) and, (iii) that from a health perspective, without revenue for R&D, in the long term, the society would lose as medicines to treat diseases would not be produced.[104]

Developing countries stressed that even though their immediate concerns were from HIV/AIDS, tuberculosis and malaria, the accessibility of many other diseases was still of concern.[105] They argued that it did not make much public health sense to address a handful of diseases and ignore the rest if the patients of both sets of diseases needed access to affordable medicine.[106]

Developed Members such as the United States and the European Union also wanted to restrict what countries were eligible to import under the system.[107] As the system was to address countries with limited or insufficient manufacturing capacity, they suggested various methods

[100] 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.
[101] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health' 99 *American Journal of International Law*, 2005, 327, 334 and 338,
[102] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 328 and 329.
[103] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 328.
[104] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 329.
[105] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 327,
[106] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 327 and 328
[107] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 325.

of classifying countries to weed who could and could not use the system.[108] For instance using statistics on national income and production capabilities.[109] Developing countries were intent on preventing the creation of distinctions among them regardless of the difference in their development and production capabilities.[110] 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 be able to use the system. Other countries would have to notify the TRIPS Council their assessment proving their lack of or limited manufacturing capacity.[111]

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. Proponents of each side are said to make their cases based on the drawbacks of the other approach.[112] 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. [113]

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 use, how was a patent holder to know when legitimate or illegitimate actions were being undertaken?[114] Eventually, the African Group and other countries end up settling for an Article 31 approach in part because the United States was unlikely to accept an Article 30 approach.[115]

---

[108] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 325.
[109] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 325.
[110] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 324.
[111] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 326.
[112] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,'328 -340.
[113]Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 329.
[114] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 329.
[115] Abbott F, 'The WTO medicines decision: world pharmaceutical trade and the protection of public health,' 340.

Initially, the Paragraph 6 System solution operated as an interim waiver.[116] 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.[117] This amendment is now known as Article 31*bis*.

2.3 The value of regional cooperation under Article 31*bis* 3

2.3.1 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.[118] It allows governments directly or indirectly, through third parties, to make, use, offer for sale, sell or import pharmaceuticals.[119] Through the Doha Declaration, WTO Members reaffirmed their ability to use *to the full* TRIPS flexibilities, including compulsory licenses, to help address public health problems and, especially, to ensure the accessibility of medicines for all.[120]

The main use of a compulsory license to countries appears to be its usefulness in price negotiators with patent holders.[121] The price of medicines is a crucial factor in their accessibility as it determines whether existing medicines can be afforded by poor patients.[122] Whether through actual imposition or the threat of imposition, governments are able to

[116] 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.
[117] World Trade Organisation General Council, *Amendment of the TRIPS Agreement: Decision of 6 December 2005*, WT/L/641, 8 December 2005.
[118] Article 31, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[119] Article 31 and 28, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[120] World Trade Organisation Ministerial Conference, *Declaration on the TRIPS Agreement and public health*, WT/MIN (01)/DEC/2, 20 November 2001, Paragraph 4.
[121] Abbott & Reichman Doha's public health legacy (2007), 970. See also Intellectual Property and Access to Medicines in Africa A Regional Framework for Access Olasupo Owoeye, 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.
[122] 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.

incentivize pharmaceutical companies to reduce the prices of their medicines.[123] 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.[124]

In addition, a compulsory license can also be used to encourage local production.[125] During negotiations of 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.[126] The local producer could either directly set up shop in the relevant country or partner with an existing local entity to promote production.[127] In this way, the better remuneration package could boost production capabilities in the less developed world.

2.3.2 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. When acting individually, they face a wide array of economic, legal and technical constraints.[128] 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.[129] The legal constraint is the case-by-case approach that compulsory licenses under TRIPS operate

---

[123] 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.
[124] Abbott F, 'The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO,' 472.
[125] 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.
[126] 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.
[127] 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.
[128] 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.
[129] 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.

which requires each Member to go through the same legal and administrative barriers in each case which increases their transaction cost.[130] The technical constraints involves the limited coordination within and between developing-country governments when engaging in compulsory licenses,[131] and defensive actions by patent holders to cut off access to sources of Active Pharmaceutical Ingredients (APIs).[132]

Other constraints involve the limited technical skills to effectively use TRIPS flexibilities, insufficient capacity to regulate medicines, external pressures against using compulsory licenses and difficulties in obtaining pricing and patent information.[133]

Scholars such as Abbott, Reichman and Musungu propose that these constraints can be solved by combining national legal and policy efforts with regional ones.[134] 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.[135] In addition, it would create economies of scale which would motivate patent holders to engage in business with them.[136]

2.3.3 The legal basis for regional cooperation under Article 31*bis* 3

Generally, regional arrangements are envisioned in the General Agreement on Tariffs and Trade (GATT) system. Article XXIV of the GATT 1948 provides for such arrangements and is

[130] 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.
[131] 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.
[132] 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.
[133] Musungu S, Villanueva S, and Blasetti R, 'Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks' South Centre, 2004, 3.
[134] 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.
[135] Musungu S, Villanueva S, and Blasetti R, 'Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks,' xiv
[136] 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.

incorporated into the GATT 1994 system through Article 1 (a) of the GATT 1994.[137] It creates a basis for the Establishment of two kinds of regional trade agreements: customs unions, free trade areas and interim arrangements to create either of the two.[138] Such agreements must be notified[139] to the WTO who will then consider and approve them.[140] It rationalizes such cooperation by recognizing that such voluntary agreements further liberalize trade between the countries party to them.[141]

Under the compulsory licensing of pharmaceutical patents, paragraph 3 of Article 31*bis* envisions regional cooperation of countries belonging to the same regional trade agreement. It allows them to export medicines produced or imported under a compulsory license to each other.[142] However, this is subject to some conditions.

Article 31*bis* 3 requires the RTA (i) to be a regional trade agreement within the meaning of Article XXIV of GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (the Enabling Clause) and, (ii) to have at least half of its membership composed of countries classified as LDCs by the United Nations. [143]

Should an RTA satisfy these conditions, its members would be able to invoke the authorization to export medicine to each other where they share the same health problem.[144] The EAC may be one such RTA. The member countries of the EAC made a notification under the Enabling Clause to the WTO Members through the Council for Trade and Development, of their intention to create the East African Community and specifically their desire to establish a

[137]Article 1 (a), *General Agreement on Tariffs and Trade,* 15 April 1994, 1867 UNTS 187.
[138] Article XXIV (4), *General Agreement on Tariffs and Trade,* 30 October 1947, 55 UNTS 194.
[139] Article XXIV (7), *General Agreement on Tariffs and Trade*, 30 October 1947, 55 UNTS 194.
[140] Article XXIV (10), *General Agreement on Tariffs and Trade*, 30 October 1947, 55 UNTS 194.
[141] Article XXIV (4), *General Agreement on Tariffs and Trade,* 30 October 1947, 55 UNTS 194.
[142] Article 31bis 3, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[143] Article 31*bis* 3, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[144] Article 31bis 3, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.

customs union.[145] The WTO, through its RTA database, has provided for the consideration process and relevant documents for this process relating to the East African Community.[146] The EAC has been recognised as a customs union and Economic Integration Agreement by the WTO.[147]

On the second requirement, the EAC can meet it as most of its members are LDCs, with only Kenya being a developing country. [148] As such, it may be able to rely on the Article 31*bis* 3 system.

2.3.4 Regional cooperation under Article 31*bis* 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.[149] 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.[150] 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.[151]

---

[145] < WTO Regional Trade Agreement Database >- Accessed on 5 January 2024.
[146] < WTO Regional Trade Agreement Database >- Accessed on 5 January 2024.
[147] < WTO Regional Trade Agreement Database >- Accessed on 5 January 2024.
[148] <https://www.un.org/development/desa/dpad/least-developed-country-category/ldcs-at-a-glance.html >- Accessed on 4 January 2024.
[149] 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.
[150] 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.
[151]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.

The countries can also opt to create a regional centre which the scholars refer to as a Regional Pharmaceutical Supply Centre (RPSC), to agree on what essential medicines are to be obtained and coordinate the procurement.[152] 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.'[153] Such a centre would involve the input of all countries as its Board of Directors would be composed of the Health Ministers of the constituent countries.[154]

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 regional compulsory license.[155] Thereafter, the RPSC would invite tenders from pharmaceutical companies and their generic counterparts to satisfy the regional demand.[156] This presents a better incentive for suppliers as the various markets are combined to generate economies of scale.[157]

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.[158] 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

[152] 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.
[153] 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.
[154] Procuring 21
[155] 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.
[156] 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.
[157] 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.
[158] 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.

future.[159] 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.[160]

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.[161] 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.[162] This could be through direct efforts or through partnering with local partners that already operate in the area.[163] Again, should the companies turn this offer down, the RPSC can approach generic manufacturers with a similar deal.[164] Abbott and Reichman believe that such efforts could lead to the creation or local manufacturing capacity akin to that developed in India during the transition period before TRIPS provisions were required to be implemented.[165]

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.

As such, 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.

---

[159] 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.
[160] Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centres,' 23.
[161] Article 31bis (3), Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994,1869 UNTS 299.
[162] Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centres,' 22 and 23.
[163] Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centres,' 22 and 23
[164] Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centres,' 23.
[165] 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.

2.4 Conclusion

This chapter has addressed the main objective by detailing the contribution that compulsory licenses under Article 31*bis* would make to access to affordable medicines in the EAC. In so doing, it discussed the development of the accessibility of medicines alongside the development of the international intellectual property regime. It traced their interaction before the TRIPS, during its implementation and the period before and after the Doha Declaration on TRIPS and Public Health.

In its second section it went through the benefits of a compulsory license including its use in price negotiation and the establishment of local production capacity. It built on this by detailing the benefits of using a regional approach as allowed by Article 31*bis* 3 rather that a single approach by a government. By looking at the proposals such as pooled procurement and regional centres for enhancing regional cooperation under the TRIPS, this chapter hopes to have showed its promising impact to the EAC RTA. The following chapter will expound on how Members were to implement TRIPS provisions, particularly, Article 31*bis* into their national legal systems to derive the benefits explored herein.

CHAPTER THREE

EXAMINING THE PLACE OF DOMESTIC LEGISLATION IN IMPLEMENTING COMPULSORY LICENSING UNDER ARTICLE 31*BIS* OF THE TRIPS AGREEMENT

3.1 Introduction

Implementation refers to putting something into practice or into effect.[166] In the WTO context, it may be defined as all the "modalities, mechanisms, and instruments that assist in the application of the WTO Agreements."[167] To implement the various WTO Agreements, scholars have considered two "distinct but interactive" levels of implementation.[168] 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.[169] This includes mechanisms such as capacity building, monitoring, supervision and enforcement all aimed at steering WTO Members towards compliance with the agreements.[170]

The second level is concerned with Members themselves and how they embed the commitments within the agreements into their national legal systems.[171] This chapter is concerned with the second level, the national level. It explores the relevance of Member's domestic legislation in implementing Article 31*bis*. In so doing, 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.

---

[166] Cambridge Dictionary.
[167] Zhang X, 'Implementation of the WTO Agreements: framework and reform' 23 *Northwestern Journal of International Law & Business*, 2, 2003, 384.
[168] Zhang, 'Implementation of the WTO Agreements: framework and reform' 384.
[169] Zhang, 'Implementation of the WTO Agreements: framework and reform' 384.
[170] Zhang, 'Implementation of the WTO Agreements: framework and reform' 387.
[171] Zhang, 'Implementation of the WTO Agreements: framework and reform' 384.

3.2 Understanding TRIPS: A prelude to Article 31*bis* implementation

Under the TRIPS we see the Agreement refer 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).[172] Due to their broad coverage of the implementation of multiple commitments, this section will discuss Articles 1.1 and 63.1 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.'[173] In its first sentence, it mandates the Members to 'give effect' to the commitments in the TRIPS Agreement.[174] This has been interpreted to create a 'basic obligation' on Members to do so by the Panel in *China- Intellectual Property Rights.*[175] 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.[176] The same Panel explained this to mean that Members are free to implement a higher standard, subject to the in-built condition.[177] It clarifies that TRIPS is only a minimum standards agreement.[178]

[172] Article 63 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[173] Article 1 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[174] Article 1 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[175] China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights, DS362, WTO Panel Report, 2009, 7.513.
[176] Article 1 (2), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[177] China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights, DS362, WTO Panel Report, 2009, 7.513.
[178] China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights, DS362, WTO Panel Report, 2009, 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 Report, 2013, 7.2682.

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.[179] Panels have interpreted this final sentence to indicate that although the TRIPS has no intention of harmonising *laws* between Members,[180] it does not grant Members the freedom to implement a lower standard.[181] Rather, it grants Members the freedom to determine the appropriate means of implementing the TRIPS provisions.[182]

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 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 (US)* confirm that *many* laws can be used to address the same intellectual property standards, even those that were not created specifically to provide for IPR protection.[183] In that case, the complainant (the United States) claimed that the EC Regulation 2081/92 did not provide for national treatment for geographical indications, and was insufficient in its protection of pre-existing trademarks that are similar to geographical indications.[184]

While the Panel agreed that the Regulation's protection was insufficient, it did not find a TRIPS violation because the EC (European Community)[185] had other laws addressing the matters such as the unfair competition laws of EC member States.[186] It made it clear that the

[179] Article 1 (3), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[180] Australia - Tobacco Plain Packaging, WTO Panel Report, 7.2682.
[181] China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights, DS362, WTO Panel Report, 2009, 7.513.
[182] China - Measures Affecting the Protection and Enforcement of Intellectual Property Rights, DS362, WTO Panel Report, 2009, 7.513.
[183] European Communities — Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, DS174, WTO Panel Report, 2006.
[184] EC — Trademarks and Geographical Indications (US), WTO Panel, 7.747.
[185] The European Communities is now known as the European Union. See https://european-union.europa.eu/principles-countries-history/history-eu/1945-59_en on 22 December 2023.
[186] EC — Trademarks and Geographical Indications US), WTO Panel, 7.750.

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.[187]

But it is not just hard law that is accepted. In *India- Patents (US),*[188] India presented "administrative instructions"(directions to the Patent Office) [189] 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."[190] 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 pertain to the subject matter of TRIPS.[191] This highlights the methods in which negotiators envisioned Members implementing the TRIPS provisions.

Turning to Article 63.1. Its interpretation by Panels and the Appellate Body is still pending. However, we can understand its expectations for Members in implementing TRIPS provisions by considering its explicit reference to certain tools. This aligns with the customary rules of interpretation in public international law as required for interpreting WTO Agreement provisions.[192]

The general rule of interpretation contained in Article 31 of the Vienna Convention on the Law of Treaties has been found to be such a rule of interpretation.[193] Article 31 mandates treaty interpretation to be done in good faith in accordance with the ordinary meaning of the

---

[187] EC — Trademarks and Geographical Indications US), WTO Panel, 7.746.
[188] India — Patent Protection for Pharmaceutical and Agricultural Chemical Products, DS50, WTO Appellate Body Report, 1998.
[189] *India — Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Appellate Body, 60. "…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."
[190] *India — Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Appellate Body, 59. However, India did not effectively justify the appropriateness of this method to fulfil its mailbox obligations.
[191] Article 63 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[192] Article 3 (2), *Understanding on the Rules and Procedures Governing the Settlement of Disputes*, 14 April 1994, 1869 UNTS 299.
[193] See United States — Standards for Reformulated and Conventional Gasoline, DS2, 1997 and, Japan — Taxes on Alcoholic Beverages, DS8, 1998.

terms of the treaty in their context and in light of the treaty's object and purpose.[194] The Appellate Body has turned to dictionary definitions[195] as a starting point for obtaining the ordinary meaning and provided that the rest of the agreement serves as context for a treaty provision.[196] The object and purpose can be gleaned from the preamble of an agreement,[197] as well as the actual terms used by negotiators reflecting their intent and purpose.[198]

Article 63.1 requires Members to either publish or make publicly available, "*laws and regulations, and final judicial decisions and administrative rulings of general application...*" that address the subject matter of the TRIPS Agreement.[199]

Laws refer to rules made by a government that state how people may and may not behave in society and business, which often mandate punishments if they do not obey, or a system of such rules.[200] A regulation is a rule or order prescribed for management or government.[201] A judicial decision is an opinion or determination of judges or courts in cases before them.[202] Administrative rulings have been defined as actions of governing or exercising authorities, government, authority, control, influence or authoritative pronouncements stemming from administrative bodies.[203]

These rules, opinions and actions are those that cover the subject matter of the TRIPS as provided within Article 63.1 first sentence. Turning to Article 63.2 as context, we can observe that such rules, opinions, and actions are those meant to be created or amended in order for a Member to implement the TRIPS. Article 63.2 states that Members ought to notify the TRIPS Council of the rules, opinions, and actions in 63.1 to assist their review of *the operation* of the

---

[194] Article 31, *Vienna convention on the law of treaties,* 1155 UNTS 331.
[195] United States — Standards for Reformulated and Conventional Gasoline, DS2, 1997, page 20.
[196] United States — Standards for Reformulated and Conventional Gasoline, DS2, 1997, page 18.
[197] United States — Import Prohibition of Certain Shrimp and Shrimp Products, DS58, 2001,153.
[198] United States — Standards for Reformulated and Conventional Gasoline, DS2, 1997, page 18.
[199] Article 63 (1), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[200] Cambridge Dictionary.
[201] Black's Law Dictionary, 4th ED
[202] Black's Law Dictionary, 4th ED
[203] European Communities and its Member States — Tariff Treatment of Certain Information Technology Products, DS375, 2011.

Agreement.[204] This suggests that such measures are contemplated for Members to put into practice (implement) the TRIPS provisions domestically.

Finally, moving to the object and purpose of the treaty, one objective of the TRIPS Agreement is its desire to reduce distortions and impediments to international trade.[205] To achieve this, its preamble recognises the need for new rules governing effective enforcement of IPRs that take into account differences in national legal systems.[206] As highlighted in the interpretations of Article 1.1, one way that the TRIPS accounts for such differences is by granting Members the flexibility to choose the means to implement the Agreement that suits their legal system and practice. As such, looked at considering the object and purpose of the TRIPS Agreement, Article 63.1 may also be seen as recognising the different methods of implementation of the TRIPS that may suit various jurisdictions of Members.

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.

3.3 The content and implementation of TRIPS Article 31*bis*.

Articles 30, 31 and 31*bis* serve as exceptions to the exclusive patent rights enshrined in Article 28 of the TRIPS Agreement.[207] As such, they provide a mechanism for Members to pursue non-trade policy interests without violating their TRIPS commitments. This section purposes to demonstrate how compulsory licensing under 31*bis* is to be implemented. It will briefly

[204] Article 63 (2), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[205] Recital 1 Preamble, *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[206] Recital 2 Preamble, Agreement *on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[207] Articles 30, 31 and 31bis, *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.

detail the requirements of Article 31*bis* and its predecessor which were explored in detail in the previous chapter before outlining its implementation.

3.3.1 The content of Article 31 and 31*bis*

Article 31*bis* is an amendment to Article 31 of the TRIPS Agreement.[208] Article 31 is considered to hold significant importance in the relationship between patents and access to affordable patented products.[209] This is because it may be used to enable accessibility of patented items that is hindered through the monopoly pricing power granted by patents.[210] 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.[211]

The provision does not explicitly define situations for granting a compulsory license except in the case of semiconductor technology.[212] It is suggested that treaty negotiators preferred to keep potential instances of use open while implementing strict safeguards.[213] The requirements listed between Article 31 (a)-(l) specify the conditions under which a compulsory license may be granted (the safeguards).[214] These provisions mandate that before resorting to a compulsory license, applicants must attempt to negotiate a voluntary license except in certain instances.[215] The Member must also ensure that the patent holder receives

[208] < Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017) >- on 28 November 2023.
[209] 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, 1.
[210] 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' 1.
[211] Articles 31, *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[212] Articles 31, *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[213] Gervais D, *The TRIPS Agreement: drafting history and analysis*, 2, Sweet & Maxwell, London, 2003, 250.
[214] Articles 31, *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[215] 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.

adequate remuneration.[216] Moreover, the compulsory license must be non-exclusive, non-assignable and primarily issued to supply the domestic market.[217] Daniel Gervais, who served as a member of one of the Negotiating Groups during the creation of TRIPS,[218] considers the safeguards a "detailed checklist" for the Members.[219]

Unfortunately, the condition in 31 (f) prevented Members most in need of a compulsory license (developing and least developed country Members) from making full use of the system. This is because it limits the potential export of patented products to countries in need, as only a limited number of exporters can comply with this requirement.[220] Paragraph 6 of the 2001 Doha Declaration on the TRIPS Agreement and Public Health identified this provision as a challenge faced by Members lacking sufficient pharmaceutical manufacturing capacities (typically LDCs and developing countries) in effectively utilizing compulsory licenses.[221]

To address this, the 2003 General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration waived certain obligations of Article 31 with respect to pharmaceutical patents.[222] The decision waived 31 (f), allowing a Member to issue a compulsory licensee fully for the export to another country and (h), preventing double remuneration by exporting and importing Members.[223] On 6th December 2005, the WTO general Council adopted the Protocol Amending the TRIPS Agreement which aimed to permanently incorporate this

[216] Articles 31 (f), *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[217] Articles 31, *Agreement on trade-related aspects of intellectual property rights*, 14 April 1994, 1869 UNTS 299.
[218] Gervais D, The TRIPS Agreement: drafting history and analysis, viii.
[219] Gervais D, The TRIPS Agreement: drafting history and analysis, 250.
[220] Note by Secretariat, Annual report on notifications and other information flows, IP/C/W/696, 2 March 2023, and 10.
[221] World Trade Organisation Ministerial Conference, *Doha Ministerial Declaration*, Adopted on 14 November 2001, WT/MIN (01)/DEC/1, 6.
[222] World Trade Organisation Ministerial Conference, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of 30 August 2003, WT/L/540.
[223] World Trade Organisation Ministerial Conference, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of 30 August 2003, WT/L/540.

waiver in order to grant special compulsory licenses to export pharmaceuticals.[224] This protocol formed the basis of Article 31*bis*.[225]

Article 31*bis* took effect in 2017[226] as an amendment to Article 31.[227] 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,[228] 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 export quantity, destination and product features of the shipment.[229]

The following section will explain how this amendment is to be implemented or realised within a Member's domestic context.

3.3.2 Implementing Article 31*bis*.

By 2017, two thirds of WTO Members had accepted this amendment.[230] However, acceptance and implementation are concepts that are 'entirely distinct.'[231] 'Acceptance' is the expression of a Member's consent that WTO Members are entitled to use the amendment to issue

[224] <WTO | TRIPS — How to accept the TRIPS and health amendment protocol > Accessed on 27 November 2023.
[225] <WTO | TRIPS — How to accept the TRIPS and health amendment protocol > Accessed on 27 November 2023.
[226] < Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017) >- on 28 November 2023.
[227] < Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017) >- on 28 November 2023.
[228] This only applies if the Member is not an LDCs as LDCs are presumed to have insufficient manufacturing capacity as per the TRIPS appendix to Article 31*bis*.
[229] Annex to Article 31bis, Agreement on trade-related aspects of intellectual property rights.
[230] World Trade Organisation, Protocol amending the TRIPS Agreement done at Geneva on 6 December 2005: notification of entry into force, 2017, WT/L/641.
[231] 'How to accept the protocol amending the TRIPS Agreement: background information for Members on procedures' World Trade Organisation <How to accept the Protocol Amending the TRIPS Agreement >- on 27 November 2023.

compulsory licenses.[232] It is merely the 'formal recognition' that Members should be able to use the system if they wish to do so.[233] Acceptance is done through depositing an instrument of acceptance with the Director General of the WTO.[234] When Members adopt implementing legislation, they are putting procedures in place to actually use it.[235] This legislative action provides a legal basis[236] to act either exclusively as an exporter or importer of pharmaceuticals or as both.[237]

It is possible for a Member to accept the amendment but not to adopt implementing legislation that allows it to use it.[238] When creating a guideline on how to accept the TRIPS amendment, a Member is not bound to adopt implementing legislation even after accepting the amendment.[239] In his quantitative research on the topic, Kampf identifies the varying timelines between Member's acceptance and implementation of Article 31*bis*.[240]

---

[232] 'How to accept the protocol amending the TRIPS Agreement: background information for Members on procedures' World Trade Organisation <How to accept the Protocol Amending the TRIPS Agreement >- on 27 November 2023.

[233] Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation' 14. See also, 'How to accept the protocol amending the TRIPS Agreement: background information for Members on procedures' World Trade Organisation <How to accept the Protocol Amending the TRIPS Agreement >- on 27 November 2023.

[234] Article X (7), Marrakesh and see also 'How to accept the protocol amending the TRIPS Agreement: background information for Members on procedures' World Trade Organisation <How to accept the Protocol Amending the TRIPS Agreement >- on 27 November 2023.

[235] 'How to accept the protocol amending the TRIPS Agreement: background information for Members on procedures' World Trade Organisation <How to accept the Protocol Amending the TRIPS Agreement >- on 27 November 2023.

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

[237] Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation' 4. See also, 'Members' laws implementing the 'Paragraph 6' system' World Trade Organisation, on 28 February 2011 < Members' laws implementing the 'Paragraph 6' system>- on 28 November 2023.

[238] 'How to accept the protocol amending the TRIPS Agreement: background information for Members on procedures' World Trade Organisation <How to accept the Protocol Amending the TRIPS Agreement >- on 27 November 2023.

[239] 'How to accept the protocol amending the TRIPS Agreement: background information for Members on procedures' World Trade Organisation <How to accept the Protocol Amending the TRIPS Agreement >- on 27 November 2023.

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

There are Members who first accept the amendment and then later execute implementing legislation.[241] This has been the favoured approach with the majority of the Members that have accepted the amendment.[242] Some Members opt to only accept the amendment but do not implement it.[243] Others simultaneously accept the amendment and implement it while the remaining adopt implementing legislation and only later do they formally accept it.[244]

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.[245] Albania implements Article 31*bis* in Law No. 9947 of 7 July 2008 on Industrial Property.[246] 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.[247] The following is an excerpt of this provision.

> 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.[248] Sections 31 and 32 provide the legal basis for Botswana to act as importers and exporters under the Article

---

[241] Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation' 6.
[242] Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation' 5. At the time Kampf wrote this piece (July 2015) 37 of the 50 Members who accepted the amendment followed this approach.
[243] Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation' 5.
[244] Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation' 5.
[245] < https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm >- Accessed on 20th January 2024.
[246] See Notification of Laws and Regulations Under Article 63.2 Of the Agreement, Albania, Council for Trade-Related Aspects of Intellectual Property Rights, IP/N/1/ALB/I/2 30 July 2010.
[247] Albania Article 50 (3), Law No. 9947 of 7 July 2008 on Industrial Property, 2008.
[248] See Main Dedicated Intellectual Property Laws and Regulations Notified Under Article 63.2 Of the Agreement, Botswana, Council for Trade-Related Aspects of Intellectual Property Rights, IP/N/1/BWA/I/3, 29 July 2013.

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. 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*. Section 32(2) speaks to Botswana's ability to import under Article 31*bis*. See the provision attached below:

> (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 31*bis* of the TRIPS Agreement applies.

Singapore's relevant law is the Patents Act 2005. 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.
>
> *[18/2008 wef 01/12/2008]*

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.[249] For instance, the Japan delegation, at the annual review of the Paragraph 6 System in October

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

2010 reported that its Patent Act which provided for the grant of non-excusive licenses for public interest reasons was broad enough to incorporate the amendment.[250]

3.4 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*.[251] However, it is domestic legislation that would enable a Member to actually 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.[252] As alluded to in the previous section, without implementing legislation or sufficient existing legislation that can incorporate Article 31*bis*, actors lack the basis to act either as exporters, importers, or both under 31*bis*. [253] Members without such legislation are unable to issue compulsory licenses 'despite the permissibility of this flexibility under the TRIPS Agreement.'[254]

Currently, 95% of WTO Members (155 of 164) have been found to have legislation implementing Article 31 (not Article 31*bis*).[255] This allows them to issue compulsory licenses,

[250] < https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm >- Accessed on 20th January 2024.
[251] 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.
[252] 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.
[253] Kampf R, 'Special compulsory licenses for export of medicines: key features of WTO members' implementing legislation' 4.
[254] 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.
[255] 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.

but they are limited to doing so primarily for domestic supply under Article 31 (f).[256] As such, in Member States where implementing legislation is lacking, this quantitative restriction under Article 31 (f) remains the status quo. This hampers their ability to maximise their importation or exportation of up to 100%.

The status quo is particularly bad for RTAs such as the EAC because its Partner States often lack manufacturing capacity.[257] What this means is that in addition to being unable to rely on 31*bis* to import pharmaceuticals, such countries may also be incapable of depending on Article 31 as importers because their access to medicines would still be hindered through the limited number of exporters willing and able to meet the condition in 31 (f). It therefore becomes even more crucial for such countries to ensure they have implementing legislation to function as pharmaceutical importers.

3.5 Conclusion

In this chapter, we have examined the critical role of domestic legislation in implementing compulsory licensing under Article 31*bis* of the TRIPS Agreement. We have explored how national laws are fundamental in translating international agreements into practical measures. Our exploration began by understanding the concept of implementation within the WTO, with a focus on the national level. We have underscored the significance of aligning domestic laws with TRIPS commitments, noting the flexibility afforded to member states in achieving this alignment.

Moving forward, we delved into the specifics of Article 31*bis*, elucidating its content and procedural requirements. Through examination of examples from various jurisdictions, we

[256] Article 31 (f), Agreement on trade-related aspects of intellectual property rights, 14 April 1994, 1869 UNTS 299.
[257] 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.

have illustrated the diverse approaches taken by member states in accepting and implementing this amendment. However, we have also identified the consequences of inadequate domestic legislation. Without robust legal frameworks in place, member states may struggle to fully utilize the flexibility offered by Article 31*bis*, potentially limiting access to essential medicines.

In essence, this chapter emphasizes the importance of ensuring that domestic laws support the objectives of international agreements. Only through such alignment can member states effectively use compulsory licenses to address public health challenges and ensure equitable access to vital medicines.

CHAPTER FOUR

ASSESSING KENYA'S CONTRIBUTION TO THE REGIONAL APPROACH IN ARTICLE 31*BIS* 3 AND THUS THE GAINS FOREGONE BY THE EAC DUE TO ITS LACK OF IMPLEMENTING LEGISLATION

4.1 Introduction

Chapters 2 and 3 lay the groundwork for a discussion on the benefits of compulsory licensing to the accessibility of medicines in the EAC. They do so by detailing and the value of compulsory licensing and the purpose of implementing legislation to utilize a compulsory license in the TRIPS system, respectively. Through our exploration in Chapter 2, it is evident that the advantages of compulsory licensing can be fully realized through its regional application within entities such as the EAC (under TRIPS Article 31*bis* 3).

This chapter examines the potential contribution of Kenya to such regional initiatives 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).

4.2 Initiatives at the EAC and the AfCFTA similar to or incorporating the Article 31*bis* system

In Chapter Three, it was established that regional compulsory licensing was particularly beneficial to smaller economies by combining their market sizes and expanding the economies of scale suppliers would enjoy by supplying the region they are combined to forma. In addition, together with strategies such as pooled procurement, local manufacturing, and the creation of regional procurement centres such regional cooperation under Article 31*bis* 3 could significantly enhance the accessibility of medicines. As a result, the following sections discuss the various regional and continental plans with regard to each of these aspects

(regional compulsory licensing, local production, pooled procurement, and regional procurement centres). To demonstrate Kenya's potential contribution to the 31*bis* system, this chapter discusses Kenya's contribution to local production and pooled procurement initiatives as these enhance the benefits of the system.

Various initiatives within Africa are dedicated to the objective of pharmaceutical accessibility. However, due to constraints in both space and time, this dissertation 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 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 African Continental Free Trade Area-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, I will illustrate the considerable advantage Kenya could contribute to the regional initiative at the EAC level. Before delving into Kenya's suitability, I will first review the initiatives.

4.2.1 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 into 4: (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. As stated in section 4.2 of this chapter, these four aspects are relevant based on our discussion in Chapter Two that revealed their usefulness in maximising the accessibility of medicines.

The EAC Partner States 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.[258] 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.[259]

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.[260]

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.[261] 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. [262]

[258] EAC Regional Intellectual Property Policy on The Utilisation of Public Health-Related WTO-TRIPS Flexibilities and The Approximation of National Intellectual Property Legislation. See Section 3.10 on Compulsory Licensing where EAC Partner States are advised to provide in their national law:

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

[259] EAC Regional Intellectual Property Policy on The Utilisation of Public Health-Related WTO-TRIPS Flexibilities and The Approximation of National Intellectual Property Legislation.
[260] Section 8 and 14, *EAC Health Protocol on Public Health Related WTO-TRIPS Flexibilities*, 2013.
[261] 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.
[262] 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.

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" [263] 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.[264] This approach involves states jointly negotiating prices with select suppliers, agreeing to purchase from certain suppliers and then individually making such purchases. [265] 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.[266] Because each EAC country has regional centres and procures pharmaceuticals separately, to demonstrate Kenya's contribution to the regional initiative in 31*bis*, I will focus on Kenya's role in local production and pooled procurement instead.

4.2.2 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. [267] It was launched to encourage the accessibility of pharmaceuticals continent wide by advancing both local production capacity and pooled

[263] East Africa Community, 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027,1.
[264] 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.
[265] 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.
[266] -<East African Procurement Forum>- accessed on 1 March 2024.

[267] United Nations Economic Commission for Africa, *Showcasing the AfCFTA-anchored Pharmaceutical Initiative: Lessons and Experiences*, 2022, 3.

procurement of medicines within Africa.[268] 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 10 pilot countries to assess the value of their contributions to such regional plans.[269]

The 10 pilot countries include Kenya and two other EAC members (DRC and Rwanda) and 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. Firstly, 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*. Secondly, 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"[270] of a healthy society. Nevertheless, despite this limitation on the scope of research, the relevant data given and analysed is general to the pharmaceutical industry which enables us to apply it to the general field of pharmaceutical access.

---

[268] United Nations Economic Commission for Africa, *Showcasing the AfCFTA-anchored Pharmaceutical Initiative: Lessons and Experiences*, 2022, 3.
[269] 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.
[270] 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.

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

4.3 Kenya's Contribution to Regional Initiatives such as the Article 31*bis* system

Unfortunately, the various EAC initiatives and their respective situational analyses and feasibility studies are more tailored towards testing the achievement of regional goals. As such, rarely do they compare different EAC states and conclude on the relative success one state would have in a project over another. The AfCFTA-anchored Pharmaceutical initiative does not suffer from this problem. Its situational analysis and feasibility study focuses on the 10 pilot African countries chosen as pioneers of the project, comparing, and contrasting them and eventually ranking the success they are likely to achieve relative to each other.

The analysis uses a framework created by drawing relevant parameters from existing literature, case studies and the databases of different regions and countries.[271] The analysis 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.

4.3.1 The Factors Predicting Success In Local Production And Pooled Procurement From The AfCFTA-Anchored Initiative Study

The AfCFTA-anchored initiative assessment underscores the advantageous position of larger countries such as Ethiopia and Kenya in undertaking local production. This is because of the

[271] 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.

corresponding rate of growth of their pharmaceutical industries.[272] 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.[273] 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.[274]

When discussing pooled procurement in regional initiatives, larger countries like Ethiopia and Kenya are mentioned as potential 'anchor' countries due to their size or large markets which attract investment.[275] Their participation in regional initiatives can thus increase the market size of the region[276] 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

[272] 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.
[273] 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.

[274] 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.
[275] 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.
[276] 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.

also for trade and industrialization, and leverages on enablers like political will, investment-friendly environments, and skilled workforces.[277]

4.3.2 Comparing Kenya and other EAC Partner States Based on the Factors Mentioned Above

The study concluded that Kenya is one of the 3 countries most capable of contributing to the success of the project (the AfCFTA-anchored Initiative) generally, the establishment of local production and the use of pooled procurement.[278] This is advantageous for Kenya in meeting national medication needs. More importantly for this paper, it also benefits the East African Community by providing an alternative to imported pharmaceutical goods and improving their bargaining power when negotiating as a group against foreign suppliers.

Some East African countries have either similar or even higher populations than Kenya. For instance Tanzania has a population of approximately 67 million and the Democratic Republic of Congo has a population of about 102 million people, while Kenya's population is about 55 million.[279] Be that as it may, Kenya boasts the largest *pharmaceutical* market size (with about 100 billion of annual pharmaceutical expenditure) [280] and is regarded as the hub of pharmaceutical manufacturing in the EAC.[281] 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.

---

[277] 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.

[278] See 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, 50-58.

[279] -<African Countries By Population (2024)>- accessed on 2 March 2024.

[280] 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 Institute, Discussion Paper 128, 2022, 7 -< Local production of essential health products in east and southern Africa >- on 28 February 2024.

[281] Machemedze R, Wade H, Kiiza A and Were N, 'Local production of essential health products in East and Southern Africa' 7. See also Mohamed N, 'East African pharmaceutical sector: opportunities and challenges' Federation of East African Pharmaceutical Manufacturers, 2013, 9.

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. To illustrate, Kenya has between 30-40 local manufacturers while Tanzania, Rwanda, and Uganda, have only 6, 1 and 9 respectively.[282] 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.

4.4 The Consequences Of Kenya's Lack Of Implementing Legislation To Access To Medicine In The EAC

As discussed previously in Chapter Two, 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 that provision.[283] 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 and thus needs express enabling

[282] Machemedze R, Wade H, Kiiza A and Were N, 'Local production of essential health products in East and Southern Africa' 7.
[283] 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.

legislation to be undertaken.[284] Without such legislation, actors lack the basis to act either as exporters, importers, or both under 31*bis*. [285]

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). Kenya has not adopted further 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*.

Countries like Kenya whose IP laws reflect Article 31 but not Article 31*bis* or the Paragraph 6 waiver, 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.

The limitation on Kenya's ability to issue compulsory licenses is felt by the EAC in at least two ways. Firstly, by not employing implementing legislation, Kenya does not have the right to use Article 31*bis.* By extension this means that even the regional initiative under 31*bis* 3 cannot lawfully be employed by Kenya. This hampers the plans of the wider EAC region to achieve regional cooperation in compulsory licensing, and pooled procurement initiatives in line with the TRIPS framework. Secondly, it also hinders the exploitation and usage 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

[284] 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.

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

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 similar to 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.[286] 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.[287] 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.

4.5 Conclusion

In conclusion, the focus on Kenya within the broader context of regional healthcare initiatives is justified roto the country's unique position, local production capacity, and the benefits it would bring the EAC when attempting to pool procurement of medicines. Kenya's significant local production capacity and pharmaceutical market size position it as a potential hub for regional pharmaceutical manufacturing, offering opportunities for advancing healthcare initiatives and enhancing access to medicines across the EAC.

However, Kenya's current lack of implementing legislation presents significant obstacles to achieving equitable healthcare outcomes and limits the scope for regional cooperation under Article 31*bis* 3. Addressing these challenges requires collaborative efforts from both national and regional stakeholders to unlock the potential of TRIPS flexibilities and promote public health within the EAC. By prioritizing the establishment of implementing legislation for

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

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

Article 31*bis* and fostering collaboration among EAC Partner States, Kenya can play a pivotal role in realizing the shared goal of ensuring equitable access to medicines for all members of the East African Community. The next chapter highlights more specific recommendations to this issue.

CHAPTER FIVE

CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This final chapter aims to offer a concise summary and present the principal findings and implications derived from the research in the preceding chapters. Specifically, attention is directed towards Research Objectives (ROs) 1, 2 and 3 as addressed in Chapters 2, 3 and 4 respectively. Having reviewed the various elements of the study, it then proposes recommendations to Kenya.

5.2 Overview of the Research Conducted

5.2.1 Research Objective One: To assess the value of a compulsory licence under Article 31*bis* in achieving access to medicines in the EAC RTA

5.2.1.1 Summary

Chapter Two evaluated the significance of compulsory licences under Article 31*bis* in improving access to medicines in the East African Community, through regional initiatives in its third paragraph. This third paragraph allows Members of a Regional Trade Agreement not to comply with certain requirements of Article 31 of the TRIPS and enables their free export and re-export of pharmaceuticals to each other. The chapter's body was divided into two broad sections.

The first section explained step-by-step the history of the accessibility of medicines before the TRIPS Agreement, during its implementation and in the aftermath of such implementation. We observed accessibility declined significantly after the birth of the TRIPS Agreement due to its grant of monopoly rights to IP holders, generating criticism of the new IP system. The second section tackled the value of regional cooperation under 31*bis*. Generally, a compulsory licence is useful because it helps reduce the prices of medicines either by enabling generic manufacturers to produce and supply the medicines at competitive (cheaper) prices or by

incentivising the original manufacturer to sell them at affordable rates. Regional action instead of single-state action is more favourable to RTAs such as the EAC. This is because it allows the developing and least developed EAC members to combine their small markets forming a larger market that in turn attracts suppliers and strengthens their power within negotiations.

5.2.1.2 Finding

a. Especially in the wake of the HIV/AIDS pandemic, existing tools, or existing versions of the tools within the TRIPS allowing Members to protect their citizens' health proved insufficient.
b. Compulsory licences were among the recognised methods of addressing the limited access to medicines because they resulted in lower prices of medicines making them affordable to poor citizens.
c. Invoking compulsory licenses regionally by RTAs would enable them to increase their accessibility to medicines by (i) incentivising suppliers with larger markets to supply to and (ii) obtaining lower prices as their bargaining power increases by combining many markets/countries.
d. These benefits would be maximised by combining the regional approach with strategies like pooled procurement and the creation of regional centres as they simplify and shorten procedures.

5.2.1.3 Implication

The Partner States of the EAC RTA would greatly benefit from such an approach in terms of their accessibility to medicines.

5.2.2 Research Objective Two: To examine the place of domestic legislation in implementing compulsory licensing under Article 31*bis* of the TRIPS Agreement

5.2.2.1 Summary

Chapter Three began by noting that of the two levels of implementation, institutional and national, that exist to adopt WTO Agreements, it focused on the latter. It aimed to explore the importance and relevance of domestic legislation to a Member intending to use a compulsory license under Article 31*bis*. It first examined in general how TRIPS provisions were intended to be given effect to give a broad understanding of the implementation of TRIPS provisions. It drew information from Articles 1.1 and 63.1 of the TRIPS, their relevant jurisprudence as well as scholarly work. This review resulted in the appreciation of a Member's laws, regulations, policies, and judicial and administrative decisions as the methods of domesticating TRIPS.

A brief overview of the history and rationale of Article 31*bis* was then set out illustrating that it serves as an amendment to Article 31 intending to address the obstacles Members face while attempting to issue a compulsory license under Article 31. Following this, the implementation of this provision took centre stage. Therein the author distinguished between 'acceptance' and 'implementation' of the provision concluding that the former was merely a Member's agreement that WTO Members should be able to issue compulsory licenses under 31*bis* should they want to. The latter, however, involves a Member adopting implementing legislation to create a legal basis to use the system.

5.2.2.2 Finding

The failure of a Member to adopt legislation implementing Article 31*bis* was found to;

a. prevent them from relying on the system either as an importer or as an exporter when in need of pharmaceutical products.
b. leave the Member with the option of using the compulsory license under Article 31 alongside the provisions obstacles (if it adopted Article 31 into its domestic legal system).
c. hinder the ability of RTAs under Article 31*bis* 3 to fully take advantage of the compulsory licensing system by utilising it collectively.

5.2.2.3 Implication

The result was that Members ought to create the relevant legislation to incorporate Article 31*bis* into their legal systems should they desire to rely on the system both individually and collectively.

5.2.3 Research Objective Three: To assess Kenya's Contribution To The Regional Approach In Article 31*bis* 3 And Thus The Gains Foregone By The EAC Due To Its Lack Of Implementing Legislation

5.2.3.1 Summary

Chapter Four substantiated the dissertation's focus on Kenya within the broader regional context, despite advocating for a regional approach to improve medicine accessibility. It explored Kenya's projected success relative to other EAC countries in regional efforts similar to or incorporating the Article 31*bis* framework. This chapter paid attention to the initiatives at the EAC level that expressly advocate for using the 31*bis* framework and supplementing initiatives that aim to achieve local production and pooled procurement which go hand in hand with the framework. It also discussed the AfCFTA-anchored Pharmaceutical Initiative because of the usefulness of its data comparing Kenya to other countries.

The analysis revealed that Kenya's significant pharmaceutical size and local production capacity, position it as a hub for regional pharmaceutical manufacturing. Its incorporation within the regional initiative could thus attract suppliers to further develop local production capacity which eventually would enable Kenya to supply its Partner States and lessen dependence on imports. This showed that Kenya's lack of implementing legislation presents an obstacle to regional cooperation under Article 31*bis* 3 by (i) limiting its ability to export 100% of the pharmaceuticals it produces to other EAC states (which also undermines the goal in the previous criterion to have Kenyan products substitute foreign ones) and (ii) hindering the ability of the EAC to combine as many markets as possible within its territory to increase its market size and negotiation ability.

5.2.3.2 Finding

Kenya's role as a developing country subject to the full breadth of TRIPS obligations, and its projected success in regional efforts including pooled procurement and local production in comparison to other EAC Partner States supports the attention paid to it by the author.

5.2.3.3 Implication

Kenya's lack of implementing legislation presents an obstacle to regional cooperation under Article 31*bis* 3 by (i) limiting its ability to export 100% of the pharmaceuticals it produces to other EAC states and (ii) hindering the ability of the EAC to combine as many markets as possible within its territory to increase its market size and negotiation ability.

5.3 Recommendations to Kenya

In light of the benefits of a regional EAC approach to compulsory licensing and the consequences of the lack of Kenyan legislation implementing Article 31*bis*, the author recommends that the Parliament of Kenya either;

a. Create such implementing legislation by drafting a law or decree that allows Kenya to use the system in Article 31*bis* as a pharmaceutical and pharmaceutical product importer, exporter, or both under the terms of Article 31*bis*, or;
b. Amend section 75 (2) (b) of the Industrial Property Act, which adopts the rule in Article 31(f) of the TRIPS Agreement that limits compulsory licenses to be used predominantly to supply the domestic market. Perhaps the amendment can create exceptions to this rule, such that it allows the requirement to be waived when the system in Article 31*bis* is invoked.

BIBLIOGRAPHY

Statutes

Industrial Property Act (Act No. 8 of 2010) of Botswana.

Industrial Property Act (No 3 of 2001) of Kenya.

Law No. 9947 of 7 July 2008 of Albania.

Patents Act 2005 of Singapore.

Treaties

Agreement Establishing the World Trade Organization.

Agreement on the Trade-Related Aspects of Intellectual Property Rights.

General Agreement on Tariffs and Trade.

Treaty for the Establishment of the East African Community.

Understanding on the Rules and Procedures Governing the Settlement of Disputes.

Vienna Convention on the Law of Treaties.

Books

Gervais D, 'The TRIPS agreement: drafting history and analysis', Sweet and Maxwell, 1998.

Owoeye O, 'Intellectual property and access to medicines in Africa, A regional framework for access,' Routledge Taylor and Francis Group, 2021.

Journal Articles

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 Journal of International Economic Law 4, 2007.

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.

Igbokwe and Tosato, 'Access to Medicines and Pharmaceutical Patents: Fulfilling the Promise of TRIPS Article 31BIS,' Faculty Scholarship at Penn Carey Law, Pennsylvania, 2022.

Musungu S, Villanueva S, and Blasetti R, 'Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks' South Centre, 2004.

Niesporek A, 'Compulsory licensing of pharmaceutical products & access to essential medicines in developing countries,' BMOS Thesis, Linköping University, Sweden, 2005.

Nyaga J, 'Implementing parallel importation and licensing mechanisms to increase access to medicines in Kenya,' unpublished LLM Thesis, Stanford University, California, 2009.

Ogendi P, 'Access to essential medicines and the utilization of compulsory licensing and parallel importation in Kenya and South Africa' unpublished thesis, University of Nairobi, Nairobi, 2011.

Reed B & Randall K, Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis, 9 Plos Medicine 1, 2012.

Taubman, Wager and Watal (eds), A handbook on the WTO TRIPS Agreement, Cambridge University Press, Cambridge, 2020.

Vincent N, 'Trip-ing up: the failure of trips article 31BIS' 24 Gonzaga Journal of International Law 1, 2020.

Wartini S, 'The legal implication of compulsory license pharmaceutical products in the TRIPS Agreement to the Protection of the right to health in developing countries,' 18 Journal Dinamika Hukum 1, 2018.

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.

Report

<WTO | TRIPS — How to accept the TRIPS and health amendment protocol>.

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.

Intellectual Property Rights Commission, WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries, 14 February 2002.

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

Promoting access to medical technologies and innovation, WIPO, <https://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf >

Reichman J, 'Procuring essential medicines under the amended TRIPS provisions: The prospects for regional pharmaceutical supply centres, Paper prepared for the Seminar on Intellectual Property Arrangements: Implications for Developing Country Productive Capabilities in the Supply of Essential Medicines, United Nations Conference on Trade and Development (UNCTAD). Palais des Nations, Geneva, Switzerland, 2006.

Secretariat, Annual report on notifications and other information flows, IP/C/W/696, 2 March 2023.

The East African Community, 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027, 2017.

The East African Community, EAC Regional Intellectual Property Policy on the utilization of public health- related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation, February 2013.

The East African Community, EAC Regional Intellectual Property Policy on the utilization of public health-related WTO-TRIPS flexibilities and the approximation of national intellectual property legislation, February 2013.

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.

World Trade Organisation Ministerial Conference, Doha Ministerial Declaration, Adopted on 14 November 2001, WT/MIN (01)/DEC/1.

World Trade Organisation Ministerial Conference, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of 30 August 2003.

World Trade Organization, Waiver from certain provisions of the TRIPS agreement for the prevention, containment, and treatment of covid-19 communication from India and South Africa, IP/C/W/669.

Online resource

'How to accept the protocol amending the TRIPS Agreement: background information for Members on procedures' <World Trade Organisation < How to accept the Protocol Amending the TRIPS Agreement> on 27 November 2023.

< https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> - Accessed on 3 January 2024.

<African Countries By Population (2024)> on 1 March 2024.

<East African Procurement Forum> on 28 February 2024.

<Frequently asked questions about TRIPS [trade-related aspects of intellectual property rights] in the WTO> on 1 March 2024.

<https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm > - > on 20th January 2024.

<https://www.eac.int/overview-of-eac> Accessed on 28 December 2023.

https://european- union.europa.eu/principles-countries-history/history-eu/1945-59_en on 22 December 2023.

United Nations Committee for Development Policy List of Least Developed Countries as of 18 November 2023 - <https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pd>

Webinar on necessity or flexibility: reflections on the negotiations for a TRIPS waiver for vaccines, <https://www.youtube.com/watch?v=6pjtJJ1kvLA on 5 August 2022>.

Working paper

Baker B, 'Kenya's intellectual property bill, 2020, and its shortcomings in adopting all lawful TRIPs public health flexibilities' PIJIP/TLS, Research Paper Series Number 53, June 2020, 'Kenya's Intellectual Property Bill, 2020, and Its Shortcomings' by Brook K. Baker on 31 December 2022.

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

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 Institute, Discussion Paper 128, 2022, 7 - <Local production of essential health products in east and southern Africa >.

Oxfam Briefing Paper 95, Patents versus patients five years after the Doha Declaration, 2006.

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.

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 - <https://www.southcentre.int/wp-content/uploads/2022/10/RP168_TRIPS-Flexibilities-and-Access-to- Medicines_EN.pdf>.