

Vawda, Yousuf A.; Shoji, Bonginkosi

Research Report

Eighteen years after Doha: An analysis of the use of public health TRIPS flexibilities in Africa

Research Paper, No. 103

Provided in Cooperation with:

South Centre, Geneva

Suggested Citation: Vawda, Yousuf A.; Shoji, Bonginkosi (2020) : Eighteen years after Doha: An analysis of the use of public health TRIPS flexibilities in Africa, Research Paper, No. 103, South Centre, Geneva

This Version is available at:

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Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa

Yousuf A Vawda and Bonginkosi Shozi



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EIGHTEEN YEARS AFTER DOHA: AN ANALYSIS OF THE USE OF PUBLIC HEALTH TRIPS FLEXIBILITIES IN AFRICA

Professor Yousuf A Vawda
BA, BProc, LLM, LLD¹
&
Mr Bonginkosi Shoji
LLB, LLM, Phd Candidate²

SOUTH CENTRE

FEBRUARY 2020

¹ Senior Research Associate, School of Law, University of KwaZulu-Natal, vawday@ukzn.ac.za.

² Doctoral Fellow with the African Health Research Flagship, University of KwaZulu-Natal, 214511633@stu.ukzn.ac.za.

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South Centre
Ch. du Champ d'Anier 17
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

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ABSTRACT

As we observe the 18th anniversary of the Doha Declaration on the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) and Public Health, it is appropriate to take stock of intellectual property developments and endeavour to present a comprehensive account of the situation in the African continent in respect of the implementation of TRIPS flexibilities, specifically those regarding access to medicines. This research paper provides an overview of the extent to which selected African countries have adopted legal and policy frameworks with regard to TRIPS flexibilities, examines the actual use of these flexibilities in enabling access to medicines in those countries, and suggests some recommendations for optimising the use of the flexibilities in pursuing public health imperatives.

Alors que nous célébrons le 18e anniversaire de la déclaration de Doha sur l'accord sur les ADPIC (accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce) et la santé publique, il convient de faire le point sur l'évolution des droits de propriété intellectuelle et de rendre compte de manière détaillée de la situation sur le continent africain en ce qui concerne la mise en œuvre des flexibilités prévues dans l'accord, en particulier celles qui concernent l'accès aux médicaments. Ce rapport de recherche donne un aperçu des cadres juridiques et politiques mis en place par certains pays africains en matière de flexibilités. Il dresse un bilan de la manière dont ces flexibilités sont utilisées pour faciliter l'accès aux médicaments dans ces pays et formule quelques recommandations afin de renforcer l'utilisation des flexibilités dans les domaines où des impératifs de protection de la santé publique l'exigent.

Al celebrarse el 18° aniversario de la Declaración de Doha sobre el Acuerdo sobre los ADPIC (Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio) y la Salud Pública, es conveniente hacer un balance de la evolución de la propiedad intelectual e informar detalladamente sobre la situación en el continente africano con respecto a la aplicación de las flexibilidades del Acuerdo sobre los ADPIC, en especial las relativas al acceso a los medicamentos. El presente documento de investigación ofrece una visión general de la medida en que determinados países africanos han adoptado marcos jurídicos y normativos con respecto a las flexibilidades del Acuerdo sobre los ADPIC, analiza el uso real de estas flexibilidades para permitir el acceso a los medicamentos en aquellos países, y sugiere algunas recomendaciones para optimizar el uso de las flexibilidades en el cumplimiento de los imperativos de salud pública.

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INTRODUCTION

For almost two decades since the advent of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),³ various scholars and institutions have undertaken research on intellectual property (IP) developments in the African region and, particularly since the adoption of the Doha Declaration on the TRIPS Agreement and Public Health⁴ in November 2001, they have increasingly focused on the domestication of TRIPS flexibilities in national law and the extent of their use.⁵ As we observe the 18th anniversary of the Declaration, it is appropriate to take stock of such developments and endeavour to present a comprehensive account of the situation in the African continent in respect of the implementation of such flexibilities, specifically those regarding access to medicines.

This research paper provides an overview of the extent to which selected African countries⁶ have adopted legal and policy frameworks with regard to TRIPS flexibilities, examines the actual use of these flexibilities in enabling access to medicines in those countries, and suggests some recommendations for optimising the use of the flexibilities in pursuing public health imperatives.

The paper begins with a background to intellectual property in Africa and of the World Trade Organization (WTO), TRIPS Agreement and the Doha Declaration. It then provides an overview of the situation in African countries and proceeds to give an account of the role of regional policy frameworks and IP organisations. The next section outlines the various flexibilities that fall into pre-grant and post-grant categories, their appearance in national legislation and the extent to which they have been utilised. Recommendations as to how States that have not yet revised their IP regulatory regimes to maximise public health-related flexibilities may do so are also made. Flexibilities outside IP and industrial property legislation i.e. competition law and policy are also discussed. The paper concludes that countries must reform their patent or industrial property laws to enable the full utilisation of

³ WTO. *Agreement on Trade-Related Aspects of Intellectual Property Rights*.

https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm (TRIPS Agreement).

⁴ WTO. *Declaration on the TRIPS agreement and public health*. (Doha Declaration).

⁵ See, for example: SF Musungu and C Oh. *The Use of Flexibilities by Developing Countries: Can They Promote Access to Medicines?* (2005) Commission on Intellectual Property Rights, Innovation and Public Health

<http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> (Musungu and Oh 2005); C Oh. *Compulsory licences: recent experiences in developing countries* (2006) Int J Intellectual Property Management. Vol 1 Nos 1/2 (Oh 2006); T Avafia et al. *The ability of select sub-Saharan African countries to utilise TRIPS Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries* (2006) tralac Working Paper No 12/2006 <http://www.section27.org.za/wp-content/uploads/2010/10/Avafia-Berger-and-Hartzenberg.pdf> (Avafia et al 2006); E Munyuki and R Machemedze.

Implementation of the TRIPS flexibilities by east and southern African countries: Status of patent law reforms by 2010 (2010) Equinet Discussion Paper 80

<http://www.equinetafrica.org/sites/default/files/uploads/documents/Diss80TRIPSupdate2010.pdf> (Munyuki and Machemedze 2010); SF Sacco. *A comparative study of the implementation in Zimbabwe and South Africa of the international law rules that allow compulsory licensing and parallel importation for HIV/AIDS drugs* (2004).

UPSpace Institutional Repository (Sacco 2004); WIPO. *Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels* (2010)

https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629 (WIPO 2010); EFM 't Hoen et al Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region (2018). *Journal of Pharmaceutical Policy and Practice* 2018; 11: 31 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6277991/> ('t Hoen 2018); Medicines Law and Policy.

The TRIPS Flexibilities Database <http://tripsflexibilities.medicineslawandpolicy.org/> (Medicines Law and Policy TRIPS Database); and BK Baker. *A Full Description of WTO TRIPS Flexibilities Available to ARIPO Member States and a Critique of ARIPO's Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities* (2019) <http://kelinkkenya.org/wp-content/uploads/2019/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf> (Baker 2019).

⁶ This contribution focuses primarily on the Anglophone countries in Africa.

TRIPS flexibilities, and that adoption and implementation of flexibilities in national systems is but a first step on the road to health for all.

BACKGROUND TO IP IN AFRICA

Africa is a huge continent, comprising some 55 independent States and a population of approximately 1.3 billion,⁷ with a wide linguistic, cultural, political, geographic and economic diversity. Although human development index values are on the rise, deprivations are found across the board. African countries occupy all but one of the bottom twenty positions on the Human Development Index.⁸ There is a correlation between healthy life expectancy and economic development. While life expectancy in the African region has recently been increasing (from 50.9 years to 53.8 years between 2012 and 2016), asymmetries exist between countries, with healthy lives highest in countries with better economies.⁹

Furthermore, the burden of disease is now driven not only by communicable but also non-communicable conditions and violence/injuries. While the levels of morbidity and mortality have dropped significantly for malaria, HIV/AIDS and diarrhoeal diseases, there is no significant reduction for non-communicable diseases.¹⁰ Many factors contribute to the state of health in the region, including the availability of health services, health system performance and health system investments.¹¹

Other research has already pointed to the inaccessibility of needed medicines to treat certain conditions, such as HIV/AIDS, because of excessive prices due to the increased level of patent protection under the TRIPS regime.¹²

More recently, a United Nations High-Level Panel directed attention to this barrier in access to medicines, observing that ‘public health-sensitive intellectual property rules and mechanisms can help address the misalignment between profit-driven innovation models and public health priorities,’ and that ‘TRIPS flexibilities ... can ensure that patents are only awarded for genuine innovation.’¹³ It concluded with recommendations to countries to, *inter alia*, adopt and apply rigorous definitions of invention and patentability that are in the best interests of public health; strengthen the capacity of patent examiners at national and regional levels to apply such rigorous standards; adopt and implement legislation that facilitates the issuance of compulsory licences; move the World Trade Organisation (WTO) to revise the paragraph 6 decision to enable a swift and expedient export of pharmaceutical products produced under compulsory licences; and a host of other public health-oriented measures.¹⁴

All WTO members can benefit from the flexibilities allowed by the TRIPS Agreement. One question that arises in this context is this: why have African countries been slow to fully incorporate the available flexibilities in their national legislation?

⁷ Worldometers, <https://www.worldometers.info/world-population/africa-population/>.

⁸ UNDP, *Summary Human Development Indices and Indicators: 2018 Statistical Update* (2018), 19, http://www.hdr.undp.org/sites/default/files/2018_summary_human_development_statistical_update_en.pdf

⁹ WHO Regional Office for Africa. *The State of Health in the WHO African region. An analysis of the status of health, health services and health systems in the context of the Sustainable Development Goals* (2018), xii, <https://www.afro.who.int/sites/default/files/sessions/documents/State%20of%20health%20in%20the%20African%20Region.pdf> (WHO 2018).

¹⁰ Ibid.

¹¹ Ibid.

¹² See, for example, EFM ‘t Hoen, *The Global Politics of Pharmaceutical Monopoly Power. Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (2009), 1, https://www.msfaaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf

¹³ United Nations. *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines. Promoting innovation and access to health technologies* (2016), 8, <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf> (UNSG High Level Panel 2016).

¹⁴ UNSG High Level Panel 2016, 9–11.

The IP legislation inherited by African countries were constructs of their colonial masters. Although these countries did not achieve anywhere near the technological prowess of the mother countries, the IP regimes of the metropolises were imposed on them. These influences originate from Great Britain, France and Portugal. Post-independence, African countries continued to implement such laws, although, to some extent, they undertook revisions to those laws.¹⁵ As a consequence, regardless of the level of their economic development, many of the developing and least developed countries in Africa continued to adopt and implement the norms, standards and levels of protection for IP of developed countries.

The result is the emergence of 'unique national IP environments' comprising statute and case law, policies and practices. Thus, 'the African IP landscape is multi-layered. In addition to relevant global and national frameworks, there are regional and sub-regional IP frameworks to consider' such as the two sub-regional IP organisations, the African Regional Intellectual Property Organisation (ARIPO)¹⁶ and the Organisation Africaine de la Propriété Intellectuelle (OAPI)¹⁷ and Regional Economic Communities (RECs).¹⁸ Adding to the diversity of the IP frameworks, one key difference is the internal arrangements between the ARIPO and OAPI Member States. In terms of the Bangui Agreement¹⁹, OAPI Member States share the same body of IP laws. ARIPO Protocols, on the other hand, had to be domesticated by Member States, resulting in each Member having its own unique national framework.²⁰ This distinction makes a significant difference to the manner in which patents granted at the regional structure are received in their respective Member countries.²¹

¹⁵ T Kongolo, *Historical Developments of Industrial Property Laws in Africa* (2013) W.I.P.O.J Issue 1 2013 Thomson Reuters (Professional) UK Limited and Contributors, 116-117 (Kongolo 2013).

¹⁶ ARIPO is the regional IP organisation of Anglophone countries in Africa and comprises the following 19 states: Botswana, eswatini, the Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Sierra Leone, Somalia, Sudan, Tanzania, Uganda, Zambia and Zimbabwe.

¹⁷ OAPI is the regional IP organization of Francophone countries in Africa and comprises the following 17 states: Benin, Burkina Faso, Cameroon, the Central African Republic, Chad, the Comoros, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Mali, Mauritania, the Niger, Senegal and Togo.

https://www.wipo.int/export/sites/www/patent_register_portal/en/docs/oapi.pdf

¹⁸ CB Ncube, *Intellectual Property Policy, Law and Administration in Africa: Exploring continental and sub-regional co-operation* (2016), 1 (Ncube 2016).

¹⁹ Bangui Agreement Relating to the Creation of an African Intellectual Property Organization (1977).

²⁰ Ncube (2016), 3.

²¹ See discussion below under the heading "Patent Examination".

WTO, TRIPS AND THE DOHA DECLARATION

This was the status of African countries at the advent of the WTO's TRIPS Agreement, which sought to introduce minimum IP standards globally. It is now widely accepted that the inclusion of IP protection in trade negotiations leading to the formation of the WTO was driven by the USA and other developed countries, in order to shore up the interests of innovators in the developed world. The proponents of the TRIPS Agreement favoured global protection as they perceived that existing obligations under the Berne²² and Paris²³ Conventions were insufficient to protect their interest at the global scale and were not being enforced adequately by many developing countries.²⁴

The question has thus been posed: 'Why did more than one hundred nations that were large net importers of intellectual property rights sign a TRIPS agreement that was so transparently against their interests as well as being an economic and health disaster for them?'²⁵ The answer lies in the asymmetrical power relations in the negotiations between the major developed countries, on the one side, and the developing and least developed countries on the other. For one, most of the latter group were not represented in the discussions of the technical details; secondly, they lacked technical expertise; and thirdly, many were overwhelmed by the dominance of US trade power and the intimidation of poorer countries with the threat of trade sanctions.²⁶

In the wake of the global AIDS pandemic, it soon became apparent that millions in the developing world did not have access to the medicines needed to stay alive. The high cost of patented anti-retrovirals (ARVs) was killing people. It drew instant attention to the relationship between patent protection and high drug prices. The world was waking up to the nightmare that the TRIPS Agreement had birthed. Rather than benefiting developing countries, the TRIPS Agreement further increased their dependency on multinational pharmaceutical companies, with the dire prognosis of escalating costs of drugs, vaccines and diagnostics with increased patent protections globally.²⁷

Developing countries, led by the African Group, requested the TRIPS Council to hold a Special Session to clarify the relationship between the TRIPS Agreement and public health, in particular, the flexibilities to which Members were entitled, and organised themselves more effectively to present a united front at the Fourth WTO Ministerial Conference in 2001 in Doha, Qatar.²⁸ Their submissions were supported by an international array of NGOs, legal scholars and technical experts, and the ensuing Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, reaffirmed the maximum use of the flexibilities and safeguards in the TRIPS Agreement.²⁹

²² Berne Convention for the Protection of Literary and Artistic Works (1887).

²³ Paris Convention for the Protection of Industrial Property (1883).

²⁴ See, for example, MJ Trebilcock and R Howse, *The Regulation of International Trade*, (1999), Routledge, 320 (Trebilcock and Howse 1999).

²⁵ P Drahos and J Braithwaite, *Who Owns the Knowledge Economy? Political Organising Behind TRIPS* (2004), The Corner House Briefing 32, 29 (Drahos and Braithwaite 2004).

²⁶ Drahos and Braithwaite (2004), 29-30.

²⁷ t Hoen (2009), 2.

²⁸ South Centre, *The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation* (2011), Policy Brief 7, 2, https://www.southcentre.int/wp-content/uploads/2013/06/PB7_-Doha-Declaration-on-TRIPS-and-Health_-EN.pdf (South Centre 2011).

²⁹ D Matthews, *Intellectual Property, Human Rights and Development. The Role of NGOs and Social Movements* (2011), Edward Elgar, 37.

The Doha Declaration is a seminal document as it foregrounds the public health concerns³⁰ of developing and least developed countries and clarifies some of the key flexibilities available under the TRIPS Agreement. These are:

- The right of Members to grant compulsory licences and the freedom to determine the grounds upon which they are granted.³¹
- The right to determine what constitutes a national emergency or other circumstances of extreme urgency, and expressly recognising that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, fall into these categories.³²
- The right of Members to determine their own exhaustion regimes without challenge, thereby facilitating parallel importation.³³
- An instruction to the TRIPS Council to find an expeditious solution to the difficulties faced by Members with insufficient or no manufacturing capacity in the pharmaceutical sector, in making effective use of the compulsory licensing provision.³⁴
- A reaffirmation of the right of least developed countries not to implement the provisions of the TRIPS Agreement in respect to pharmaceuticals until 1 January 2016 and to seek further extensions of this transition period flexibility.³⁵

The Doha Declaration has thus paved the way for the most public health access-friendly IP framework since the TRIPS Agreement.

³⁰ “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.” Doha Declaration, para 4.

³¹ Doha Declaration, para 5b.

³² Doha Declaration, para 5c.

³³ Doha Declaration, para 5d.

³⁴ Doha Declaration, para 6.

³⁵ Doha Declaration, para 7.

THE SITUATION IN AFRICAN COUNTRIES

This study provides an overview of the legislation relating to health-related aspects of the IP regimes of 28 African States. The study highlights some of the core flexibilities available to these States, with a particular focus on flexibilities available to the WTO Least Developed Countries (LDCs), in terms of the TRIPS Agreement. This analysis also includes a discussion of the extent to which TRIPS flexibilities have been used by African States to secure access to medicines.

The 28 States examined in this study are affiliated with at least one of three, major regional bodies in the African continent, which have an interest in the IP regimes of their Member States: ARIPO, the Southern African Development Community (SADC) and the Eastern African Community (EAC). The 28 States are Angola, Botswana, Burundi, Comoros, the Democratic Republic of Congo (DRC), Gambia, Ghana, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Rwanda, Sao Tome and Principe, the Seychelles, Sierra Leone, South Africa, South Sudan, Sudan,³⁶ eSwatini, Tanzania, Uganda, Zambia, Zanzibar, Zimbabwe.

The majority of the these States are in a position to capitalise on these flexibilities because, as LDCs, they are not required to adhere to the IP standards required in the terms of the TRIPS Agreement.³⁷ The 15 LDC States can thus benefit from the LDC transition provision.³⁸ Four of them are not WTO Member States at present, namely, Sao Tome and Principe,³⁹ South Sudan,⁴⁰ (North) Sudan⁴¹ and Zanzibar, and therefore not obliged to implement any of the WTO treaties, including the TRIPS Agreement.

Similar studies to this one have previously observed that, notwithstanding the relative freedom afforded to them, many African States have been slow to undertake the necessary reforms to their IP regulatory regimes in order to take advantage of the LDC transition and other flexibilities.⁴² In a recent review on the patent laws of several African States, Machededze and Munyuki observed that in Eastern and Southern Africa, most of the IP laws currently in effect were in existence long before the TRIPS Agreement, a vestige of colonial rule.⁴³ As such, many States did not provide for certain flexibilities, and even where flexibilities were provided for, the authors observe that they were not being implemented.

Recognising the lack of progress by countries on the continent in incorporating TRIPS flexibilities into their IP legislation, and in the wake of the triple epidemics of HIV/AIDS, TB and malaria, the African Union in 2012 adopted the Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa.⁴⁴ The Roadmap defined its

³⁶ Sudan is referred to as (North) Sudan in this work for the purpose of distinguishing it from South Sudan.

³⁷ Article 66.1 of the TRIPS Agreement.

³⁸ These States are Angola, Burundi, Comoros, DRC, Gambia, Lesotho, Madagascar, Malawi, Mozambique, Rwanda, Sierra Leone, Uganda, Zambia and Zimbabwe.

³⁹ Sao Tome and Principe has WTO observer status. See WTO *Members and Observers*, https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

⁴⁰ South Sudan is in the process of accession. See WTO, *South Sudan*, https://www.wto.org/english/thewto_e/acc_e/a1_south_sudan_e.htm.

⁴¹ (North) Sudan is in the process of accession. See WTO, *Sudan*, https://www.wto.org/english/thewto_e/acc_e/a1_soudan_e.htm.

⁴² See, for example, Musungu and Oh 2005; Avafia et al 2006; SF Musungu, S Villanueva and R Blasetti. *Utilizing Trips Flexibilities For Public Health Protection Through South-South Regional Frameworks* (2004), South Centre <http://apps.who.int/medicinedocs/pdf/s4968e/s4968e.pdf> (Musungu et al 2004) ; Thorpe, *Study on the Implementation of the TRIPS Agreement by Developing Countries* (2002), Commission on Intellectual Property Rights http://www.iprcommission.org/papers/pdfs/study_papers/sp7_thorpe_study.pdf (Thorpe 2002).

⁴³ Munyuki and Machededze (2010).

⁴⁴ African Union. *Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa* (2012) https://apf.francophonie.org/IMG/pdf/annexe_2.pdf (AU Roadmap on Shared Responsibility 2012).

solutions around three strategic pillars: diversified financing, access to medicines and enhanced governance.⁴⁵ One of the priority actions identified under the access to medicines pillar was to:

‘Create a legislative environment that incorporates the full use of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) flexibilities and develops awareness to avoid the incorporation of "TRIPS-plus" measures in trade agreements.’⁴⁶

This continental declaration was intended to inform the responses of countries in the crafting of their IP regimes and to guide their negotiations on trade.

As a result of greater awareness of the necessity for legal reform to support implementation of the TRIPS flexibilities, the past decade has seen an increase in the number of states that have reworked their IP regimes. Botswana, Burundi, Kenya, Liberia, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Uganda and Zambia have all had promulgated new laws regulating IP since 2009 (see Table 1).

⁴⁵ AU Roadmap on Shared Responsibility, 2.

⁴⁶ AU Roadmap on Shared Responsibility, 3.

THE ROLE OF REGIONAL POLICY FRAMEWORKS

a) *EAC TRIPS Policy*

Interestingly, the majority of the recent reform has emanated from the EAC;⁴⁷ all its Member States (with the exception of South Sudan) have reformed their patent laws since the TRIPS Agreement came into effect. This is likely due to the EAC having actively campaigned for such reforms, as is evident from the congruence of language and intent as proposed by the EAC's Regional Intellectual Property Policy.⁴⁸ The main objective of this policy was to guide the EAC Partner States on recalibrating national IP legislation in order to enable them to fully utilise the TRIPS flexibilities. It examined the IP policies of its Member States and concluded that, in order to promote access to medicines, they ought to implement the following policy changes, as necessary:

1. Include the LDC transition provision in their national IP laws and abolish 'mailbox' patent examination practices;⁴⁹
2. Enforce stricter patentability criteria;⁵⁰
3. Exclude from patentability natural substances, new uses of known substance, and derivatives of medical products that do not show significantly enhanced therapeutic efficacy or significant superior properties;⁵¹
4. Strengthen provisions relating to research exceptions;⁵²
5. Provide for the early working (bolar) exception;⁵³
6. Provide for test data protection;⁵⁴
7. Provide for extensive disclosure in patent applications to facilitate thorough search and examination;⁵⁵
8. Provide for pre- and post-grant administrative opposition of patents;⁵⁶
9. Provide for international exhaustion in all forms of IP;⁵⁷
10. Provide for the grant of compulsory licences on grounds and conditions that enable access to medicines; and⁵⁸
11. Include in the patent laws provisions that discourage unfair and/or anti-competitive practices.⁵⁹

This policy further provides detailed guidance on the implementation of these proposals.⁶⁰

b) *SADC Strategy*

Attempts to influence policy development in African States to capitalise on TRIPS flexibilities were also made in the SADC region,⁶¹ most recently in the form of the Strategy for Pooled

⁴⁷ The EAC is a regional intergovernmental organisation of six States, comprising Burundi, Kenya, Rwanda, South Sudan, Tanzania and Uganda.

⁴⁸ Eastern African Community, *Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation* (2013), <https://www.cehurd.org/wp-content/uploads/downloads/2013/05/EAC-TRIPS-Policy.pdf> (EAC Regional IP Policy).

⁴⁹ EAC Regional IP Policy, 12

⁵⁰ EAC Regional IP Policy, 13

⁵¹ EAC Regional IP Policy, 14

⁵² EAC Regional IP Policy, 15.

⁵³ EAC Regional IP Policy, 16.

⁵⁴ EAC Regional IP Policy, 16.

⁵⁵ EAC Regional IP Policy, 17.

⁵⁶ EAC Regional IP Policy, 18.

⁵⁷ EAC Regional IP Policy, 18.

⁵⁸ EAC Regional IP Policy, 20.

⁵⁹ EAC Regional IP Policy, 21.

⁶⁰ EAC Regional IP Policy, 21.

Procurement of Essential Medicines and Health Commodities.⁶² The development of the SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities was motivated by the need to achieve the SADC's priority objective, 'to improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines.'⁶³ It identifies several challenges with regard to procurement and supply management in the SADC region. In the table provided in the strategy document, it is recorded that no information was provided on the use of flexibilities in this region.⁶⁴ In response to this difficulty, a key strategic objective of this policy is to ensure that TRIPS exemptions available for access to medicines are implemented by Member States.⁶⁵ This was to be achieved by providing the necessary support to fully utilise the TRIPS exemptions.

Since the inception of the Strategy in 2013, only Mozambique, the Seychelles and Zambia have revised their patent law regimes (see Table 1).

Given these recent developments, it is opportune to revisit the situation regarding the implementation of TRIPS flexibilities in Africa.⁶⁶ However, occasionally the IP regimes in force do not necessarily reflect the actual practice in each of these States, for example, in the DRC, it has been reported that Law No. 82-001, January 1982, is not being enforced.⁶⁷ This appears to be a report compiled by US embassies as advice to companies seeking to do business abroad (and possibly also for the compilation of the 301 Watch Lists under the US Trade Act of 1974). In any event, this law pre-dates the TRIPS Agreement, and the DRC appears to be utilising the LDC pharmaceutical transition flexibility in order to import ARVs, as it did in 2005.⁶⁸

⁶¹ SADC is a Regional Economic Community comprising 16 Member States: Angola, Botswana, Comoros, Democratic Republic of Congo, Eswatini, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Tanzania, Zambia and Zimbabwe.

⁶² SADC *Strategy for Pooled Procurement of Essential Medicines and Health Commodities, 2013-2017* https://www.sadc.int/files/7614/1898/8449/SADC_Strategy_for_Pooled_Procurement_of_Essential_Medicines_and_Health_Commodities.pdf (SADC).

⁶³ SADC, 2.

⁶⁴ SADC, 9.

⁶⁵ SADC, 17.

⁶⁶ While this study focuses on Member States of ARIPO, the EAC and SADC, further research will be conducted on the remaining African States.

⁶⁷ <https://www.export.gov/article?id=Congo-Democratic-Republic-Protection-of-Property-Rights>.

⁶⁸ See Medicines Law and Policy, *TRIPS Flexibilities Database*, <http://tripsflexibilities.medicineslawandpolicy.org/> (TRIPS Flexibilities Database).

THE ROLE OF REGIONAL IP ORGANISATIONS

In addition to the regional policy frameworks, which have an impact on countries' ability to reform their IP legislation, regional IP organisations play a significant role in shaping the Member countries IP system. In this regard, the situation of ARIPO⁶⁹ is instructive. A 2014 study on the ARIPO Protocol on Patents⁷⁰ revealed that the successful use of pre-grant TRIPS flexibilities by countries in the EAC, for example, has been constrained by the workings of ARIPO, which processes the majority of patent applications for that region. Its current *modus operandi* 'does not facilitate the full use of TRIPS flexibilities and instead erects patent barriers to the importation and local production of affordable medicines.'⁷¹ The study proceeds to make a number of recommendations at both the national level and the ARIPO regional level, the key among which are the amendment to the Harare Protocol to exempt LDCs from the grant of its pharmaceutical patents, and the adoption of rigorous patent examination and disclosure standards to weed out evergreening.⁷² A recent analysis of the ARIPO-commissioned 'Comparative Study of the Industrial Property Laws of ARIPO Member States' criticised the study for 'its failure to address the vast majority of TRIPS flexibilities' that are available to its Members.⁷³ The criticisms include, among others, the lack of substantive discussion on rigorous patentability standards; on the full range of allowable non-inventions and exclusions; on research and education, as well as other exceptions permitted under TRIPS Article 30; on disclosure requirements; on the prerogative of governments to define the grounds for compulsory licences; and on the use of competition policy to address abuse of patents. In addition, the Comparative Study was criticised for providing inaccurate and incorrect advice on various issues: the suggestion that Members consider shortening the period of patent protection rather than eliminating them as permitted by TRIPS Article 66.1, read together with subsequent WTO decisions to extend the transition period; pre- and post-grant opposition; parallel importation; and, regarding enforcement measures, the flexibility of limiting the remedies granted to patent holders for infringement.⁷⁴

⁶⁹ Countries currently Members of ARIPO are Botswana, The Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Sierra Leone, Somalia, Sudan, Swaziland, Uganda, United Republic of Tanzania, Zambia and Zimbabwe.

⁷⁰ S Shashikant. *The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines* (2014), South Centre Research Paper No 56, https://www.southcentre.int/wp-content/uploads/2014/11/RP56_The-ARIPO-Protocol-on-Patents_ENI.pdf (Shashikant 2014)

⁷¹ Shashikant (2014), 45.

⁷² Shashikant (2014), 46.

⁷³ BK Baker. *A Full description of WTO TRIPS Flexibilities Available to ARIPO Member States and a Critique of ARIPO's Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities* (2019) <http://kelinkkenya.org/wp-content/uploads/2019/05/ARIPO-Member-States-obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019.pdf> (Baker 2019).

⁷⁴ Baker (2019), 39-41.

Table 1: Overview of African States and Their Patent Laws

STATE	LDC Status	Regional Org.	Patent Law
Angola	LDC	SADC	Industrial Property Law, No. 3 of 1992
Botswana	Non-LDC	ARIPO, SADC	Industrial Property Act, 2010 (Act No. 8 of 2010)
Burundi	LDC	EAC	Industrial Property Law, No. 1 of 2009
Comoros	LDC	SADC	Law of July 5, 1844, on Patents for Inventions
DRC	LDC	SADC	Law No. 82-001, January 1982
Gambia	LDC	ARIPO	Industrial Property Chapter 95:03 Act 12 of 1989
Ghana	Non-LDC	ARIPO	Patents Act, 2003 (Act 657)
Kenya	Non-LDC	ARIPO, EAC	Industrial Property Act, (Act No. 3 of 2001 as amended up to Act No. 11 of 2017)
Lesotho	LDC	ARIPO, SADC	Industrial Property Amendment Act, 1997
Liberia	LDC	ARIPO	Liberia Intellectual Property Act, 2016
Madagascar	LDC	SADC	Ordinance No. 89-019 Establishing Arrangements for the Protection of Industrial Property in Madagascar (of July 31, 1989)
Malawi	LDC	ARIPO, SADC	Patents Act (Chapter 49:02) (1958)
Mauritius	Non-LDC	SADC	Patents, Industrial Designs and Trademarks Act 2002
Mozambique	LDC	ARIPO, SADC	Industrial Property Code (approved by Decree No. 47/2015 of December 31, 2015)
Namibia	Non-LDC	ARIPO, SADC	Industrial Property Act, 2012 (Act No. 1 of 2012)
Rwanda	LDC	ARIPO, EAC	Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property
Sao Tome and Principe	Non-WTO	ARIPO	Industrial Property Code Decree-Law No. 23/2016
Seychelles	Non-LDC	SADC	Industrial Property Act 2014 (Act No. 7 of 2014)
Sierra Leone	LDC	ARIPO	The Patents and Industrial Design Act, 2012
South Africa	Non-LDC	SADC	Patents Act, 1978 (as amended)
South Sudan	Non-WTO	EAC	Patent Law No. 58 of 1971
(North) Sudan	Non-WTO	ARIPO	Patent Law No. 58 of 1971
eSwatini	Non-LDC	ARIPO, SADC	Industrial Property Law, No. 6 of 1997
Tanzania	LDC	ARIPO, SADC, EAC	Patents Act, 1987
Uganda	LDC	ARIPO, EAC	The Industrial Property Act, 2014
Zambia	LDC	ARIPO, SADC	The Patents Act, 2016 (Act No. 40 of 2016)
Zanzibar	Non-WTO	EAC	Industrial Property Act No. 4 of 2008
Zimbabwe	Non-LDC	ARIPO, SADC	The Patents Act [Chapter 26:03] (amended by Act 9 of 2002)

CATEGORIES OF TRIPS FLEXIBILITIES

TRIPS flexibilities can broadly be arranged in two categories: pre-grant and post-grant. Pre-grant flexibilities are those available before the grant of a patent and normally concern the granting process. They involve preventing the issuing of patents for products that do not merit a patent for lack of innovative or novel content, or because there is no obligation to grant patents. Post-grant flexibilities refer to exceptions that allow for governments (or other interested parties) to engage in activities—for example, those that are necessary to promote access to healthcare—that would otherwise amount to an infringement of patent rights.⁷⁵

In examining the implementation of TRIPS flexibilities in Africa, this section will outline the various flexibilities that fall into each of these categories, their appearance in national legislation and the extent to which they have been utilised. We also make recommendations as to how States that have not yet revised their IP regulatory regimes to maximise public health-related flexibilities, may do so.

The pre-grant flexibilities examined in this study are the following:

- Adoption of the LDC transition period
- Patentability criteria
- Patent examination
- Pre-grant opposition

The post-grant flexibilities include the following:

- Minimum patent term
- Regulatory review exception (also known as the 'Bolar exception')
- Non-voluntary licences (compulsory licensing and government use)
- Research exception
- Parallel importation
- Post-grant opposition

a) Pre-Grant Flexibilities

i) Adoption of the LDC transition period

In terms of Article 66.1 of TRIPS, LDCs have been granted a transition period, during which they are not obligated to enforce certain provisions of the TRIPS agreement, including the provision requiring WTO Members to provide patent protection for pharmaceuticals.⁷⁶ These provisions were inserted in recognition of the special needs of LDCs, their economic, financial and administrative constraints, and the need to afford them the policy space to enable the creation of a viable technological base.⁷⁷ The general LDC transition period was previously to last until 1 January 2006 but has since been extended twice, the first time to 1 July 2013, and most recently, to 1 July 2021.⁷⁸ With respect to the additional transition period for pharmaceutical patents, the initial period was due to run (following paragraph 7 of

⁷⁵ Adapted from WHO, *The role of intellectual property in local production in developing countries: Opportunities and challenges* (2016). Available at https://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf

⁷⁶ https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

⁷⁷ Article 66.1 of TRIPS.

⁷⁸ WTO, Extension of the Transition Period Under Article 66.1 for Least Developed Country Members (IP/C/64, June 12, 2013), para 1.

the Doha Declaration) from 1 January 2002 until 1 January 2016. This has subsequently been extended to 1 January 2033, or until a country ceases to be an LDC.⁷⁹

This flexibility has been utilised by several States in order to secure access to medicines, particularly ARVs. The Medicines Law & Policy's TRIPS Flexibilities Database lists a total of 40 uses of this flexibility by 28 African countries. They are (with the year of use in brackets):⁸⁰

1. Angola (2005),
2. Benin (2004, 2007 and 2009),
3. Burkina Faso (2005),
4. Burundi (2005),
5. Cape Verde Islands (2004),
6. Central African Republic (2004 and 2005),
7. Chad (2004 and 2007),
8. Comoros (2007),
9. Djibouti (2007),
10. Democratic Republic of Congo (2005),
11. Eritrea (2005),
12. Gambia (2004 and 2007),
13. Guinea (2004 and 2005),
14. Guinea Bissau (2005),
15. Lesotho (2004 and 2006),
16. Malawi (2004 and 2005),
17. Mauritania (2004),
18. Mozambique (twice in 2005),
19. Niger (2004 and 2008),
20. Rwanda (twice in 2007),
21. Senegal (2006),
22. Sierra Leone (twice in 2009),
23. South Sudan,
24. Sudan,
25. Tanzania (2008),
26. Togo (2004, 2008 and 2009),
27. Uganda (2006), and
28. Zambia (twice in 2004, and 2008).

In some cases, this use has occurred even though, strictly speaking, it is contrary to the existing law.⁸¹ Several States have, however, endeavoured to secure an enabling policy environment by including the transition provision into their patent laws (see Table 2).⁸² One such state is Burundi, where Article 17 of the Industrial Property Law No 1 of 2009 relating to subject matters that are not patentable States: 'Pharmaceutical products, up until January 1, 2016'. This provision, however, does not provide for the possibility of the extension of this transition period beyond January 1, 2016, as is currently allowed under the TRIPS Agreement.

⁷⁹ WTO Council for Trade-Related Aspects of Intellectual Property Rights, Extension of the Transition period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, D of the Council for TRIPS of 6 November 2015, IP/C/73 (Nov. 6, 2015).

⁸⁰ Medicines Law and Policy, *TRIPS Flexibilities Database*, <http://tripsflexibilities.medicineslawandpolicy.org/> (TRIPS Flexibilities Database).

⁸¹ For instance, in the case of Gambia, pharmaceuticals were regarded as patentable as per section 3 Industrial Property Chapter 95:03 Act 12 of 1989.

⁸² These States are Burundi, Liberia, Rwanda and Zanzibar.

For countries such as Angola, whose existing IP legislation excludes pharmaceuticals,⁸³ no legislative changes may be required until such time the transition period expires or it ceases to be an LDC.

Despite the fact that pharmaceuticals are formally excluded from patentability in some of the African LDCs,⁸⁴ this flexibility does not appear to be utilised in all these States. In the case of Madagascar, Thorpe asserts that the provisions of TRIPS article 27.1 are being applied instead of the domestic law.⁸⁵

An additional burden that hinders access to medicines relates to LDCs (and non-WTO States) that are signatories to the Harare Protocol,⁸⁶ namely, ARIPO Member States, which are required to recognise the pharmaceutical patents granted through the ARIPO filing mechanism, even where their domestic laws exclude the patenting of pharmaceuticals, unless they notify the ARIPO office otherwise. Such patents are likely to be invalid at the national level but create several problems for the countries involved. At a practical level, countries often struggle to communicate their objection to ARIPO-approved patents within the six-month period, as required, due to capacity constraints, with the result that patents are granted by default.⁸⁷ Secondly, 'the existence of an ARIPO issued patent certificate creates an ambiguous legal environment, which could hinder importation of generic medicines and deter generic manufacturers from local production. It also negates the intended impact of incorporating the LDC pharmaceutical exemption in national patent legislations.'⁸⁸ Finally, such ambiguity potentially nullifies the additional flexibility provided in Article 31*bis* of the TRIPS Agreement, which enables regional pooled procurement of medicines to be freely circulated within a regional trade agreement regime in which the majority of countries are LDCs.⁸⁹

Recommendations

- 1. LDCs should adopt the extended pharmaceutical transition period in their domestic law and insert language to the effect that the exclusion of pharmaceutical products and processes will be effective for the duration of all extensions granted, or until the country ceases to be an LDC.**
- 2. In addition, LDCs should amend their legislation exempting them from complying with any TRIPS provisions, on the same terms as described in 1.**
- 3. LDCs (and developing countries) should insert an express provision in their legislation waiving the 'domestic market' requirement of Article 31(f) of TRIPS and enabling them to engage in co-operative purchasing arrangements involving the production of, import from and export to other LDCs and**

⁸³ Article 4(c) Industrial Property Law, No. 3 of 1992.

⁸⁴ These States are Liberia, and Madagascar.

⁸⁵ Thorpe (2002), 11.

⁸⁶ These States are Ghana, Lesotho, Liberia, Malawi, Mozambique, Rwanda, Sao Tome and Principe, Sierra Leone, South Sudan, (North) Sudan, eSwatini, Tanzania, Uganda and Zambia.

⁸⁷ Associacao CSARJoV, Angola and 60 others. *Civil Society Proposals to Address Policy and Legal Incoherencies in the Harare Protocol that Impact Access to Health Technologies in ARIPO Member States* (2019), 13. https://www.kelinkkenya.org/wp-content/uploads/2019/06/CSO_TRIPSFlexibilitiesProposalsForARIPOFinal-with-sign-ons-4-6-19.pdf (Civil Society ARIPO Proposals 2019).

⁸⁸ See Civil Society ARIPO Proposals (2019), 14.

⁸⁹ Article 31*bis* 3 reads: 'With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement ... at least half of the current Membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.'

- developing countries that are party to a regional trade agreement of which the majority are LDCs, as envisaged by Article 31 *bis* of the TRIPS Agreement
4. Those LDCs that are signatories to the Harare Protocol wherein patents granted by ARIPO are applicable in their countries unless they opt-out, should immediately reject all such patents, inform ARIPO accordingly and seek an amendment to the Protocol to expressly exempt them from recognising such patent grants.

ii) *Patentability Criteria*

The TRIPS Agreement requires that patents be granted for inventions that are new, involve an inventive step and are capable of industrial application. It also requires that patents shall be available and their rights enjoyable 'without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.' Finally, it allows certain exclusions from patentability for inventions that violate public order and morality, human, animal and plant life or the environment; diagnostic, therapeutic and surgical methods for treating humans and animals; and plants and animals other than micro-organisms, and essential biological processes for their production (other than non-biological and microbiological processes).⁹⁰ As the key terms in these provisions are not further defined in the TRIPS Agreement, countries have relative freedom in determining their patentability criteria spelled out in article 27.1, read together with other treaty provisions.⁹¹ While countries cannot discriminate based on the field of technology, the provision 'does not prevent States from treating different situations differently': '(d)ifferentiation may relate to the requirements of patentability, patent eligibility and disclosure ... to the exclusion of subject matter from patentability, as well as to the scope of protection.'⁹² Exemplars of the use of the flexibility related to patentability criteria, which set a high bar for what inventions should be patentable, are to be found in section 3(d) of India's Patents Act of 2005⁹³ (no new forms or new uses, among others, of a known substance unless enhanced efficacy is proven), and Argentina's patent examination guidelines,⁹⁴ which include a higher 'discovery' standard than India by preventing patents on any new form of known substances, regardless of enhanced efficacy, and which direct patent examiners to reject, in general, new uses, new forms and new formulation patents, , among other relatively minor changes to drugs, as well as broadly defined Markush claims.⁹⁵ The guidelines aim to prevent patent evergreening by limiting the grant of patents to genuine innovations, essentially new chemical entities.

Few African countries have adopted any detailed criteria close to these exemplars, with the result that the practice of evergreening is commonplace.⁹⁶ The study countries may be

⁹⁰ Article 27.1, 27.2 and 27.3 of the TRIPS Agreement.

⁹¹ Article 1.1 of TRIPS permits Members the freedom to determine the appropriate method of implementing the provisions within their own legal system and practice; Article 7 speaks to one of the objectives as being to contribute to the mutual advantage of producers and users of inventions in a manner conducive to social and economic welfare; and the principle in Article 8 States that Members may adopt measures to protect public health and nutrition.

⁹² Max Planck Institute. *Declaration on Patent Protection: Regulatory Sovereignty under TRIPS* (2014), 4, <http://www.mpg.de/8133454/Patent-Declaration1.pdf> (Max Planck Institute 2014).

⁹³ The section disallows patents on mere discoveries of new forms of existing substances unless they evidence enhanced efficacy, and also new uses of known substances.

⁹⁴ Argentina. *Joint Resolution No. 118/20012, 546/2012 and 107/2012 of May 2, 2012, of the Ministry of Industry, Ministry of Health and the National Industrial Property Institute, approving the Guidelines for the Examination of Patent Applications of Pharmaceutical and Chemical Inventions*, Date of Entry into Force: 16 May 2012 <http://www.wipo.int/wipolex/en/details.jsp?id=13007> (Argentine Patent Examination Guidelines 2012).

⁹⁵ See also CM Correa. *Guidelines for the examination of patent applications relating to pharmaceuticals: Examining Pharmaceutical Patents from A Public Health Perspective* (2015) UNDP. https://www.undp.org/content/dam/undp/library/HIV-AIDS/UNDP_patents_final_web_2.pdf (Correa 2015).

⁹⁶ See, for example, YA Vawda. Country Case Study: South Africa. In CM Correa (ed). *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (2013), South Centre, 223-262 <https://www.southcentre.int/product/pharmaceutical-innovation-incremental-patenting-and-compulsory-licensing/> (Vawda 2013).

divided into two categories for convenience: (a) those that provide no detail beyond requiring that the criteria for patentability are those stipulated in TRIPS Article 27.1 and (b) those that have attempted to provide some definition by articulating additional exclusions from patentability.

The first category of countries includes Botswana, Burundi, Comoros, Gambia, Ghana, Lesotho, Liberia, Madagascar, Malawi, Mauritius, Mozambique, Seychelles, South Africa, Sierra Leone, South Sudan, (North) Sudan, eSwatini, Uganda and Zimbabwe.

The second category includes the following countries, followed by the extent of variation in their legislation to refine their patentability requirements:

- Angola: contains an additional non-patentable invention relating to 'food and chemical-pharmaceutical products and medicines intended for human or animal consumption.'⁹⁷
- Burundi: contains the additional exclusion of 'natural substances, even if they had been purified, synthesized or isolated in another manner.'⁹⁸
- Kenya: also excludes 'public health related methods of use or uses of any molecule or other substance whatsoever used for the prevention or treatment of any disease which the Minister responsible for matters relating to health may designate as a serious health hazard or as a life threatening disease.'⁹⁹
- Namibia: also excludes 'new uses, methods of use, forms, properties of a known product or substance and already used for specific purposes and changes of shape, dimensions, proportions or materials in the subject matter applied for, except where the qualities of the subject matter are essentially altered or where its use solves a technical problem that did not previously have an equivalent solution.'¹⁰⁰
- Rwanda: excludes 'substances, even if purified, synthesized or otherwise isolated from nature; nevertheless, this provision shall not apply to the processes of isolating those substances from their original environment', 'known substances for which a new use has been discovered' and 'pharmaceutical products, for the purposes of international conventions to which Rwanda is party.'¹⁰¹
- Sao Tome and Principe: additionally excludes 'substances, materials, mixtures, elements or products of any type, resultant from atomic nuclear transformation', 'processes for cloning human beings' and 'biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature.'¹⁰²
- Tanzania: also provides for the temporary exclusion from patentability so that 'inventions which concern certain kinds of products, or processes for the manufacture of such products, may, by statutory instrument be extended for further periods, each such period not exceeding ten years.'¹⁰³
- Uganda: excludes pharmaceuticals by virtue of its LDC status.¹⁰⁴
- Zambia: excludes 'DNA, including complementary DNA sequences, cells, cell lines and cell cultures and seeds'; 'new uses of a known product, including the second use of a medicine'; 'juxtaposition of known inventions or mixtures of known products or alteration of the use, form, dimensions or materials, except where in reality they are so combined or merged that they cannot function separately or where their

⁹⁷ Article 4(c) Law No 3/92 of February 28, 1992.

⁹⁸ Article 3 Law No 1/13 of July 28, 2009.

⁹⁹ Section 21(3)(e) Industrial Property Act, 2001 (Act No. 3 of 2001, as amended up to Act No. 11 of 2017)

¹⁰⁰ Section 17(1)(j) Industrial Property Act, 2012 (Act No. 1 of 2012).

¹⁰¹ Article 18.4, 18.5 and 18.8 respectively of Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property.

¹⁰² Article 1(h), 2(a) and 2 (e) of Intellectual Property Code (approved by Decree-Law No. 23/2016).

¹⁰³ Section 13 Patents (Registration) Act, Cap 217.

¹⁰⁴ Section 8.3(f) of the Industrial Property Act, 2014.

characteristic qualities or functions have been so modified as to produce an industrial result or use not obvious to a person skilled in the art'; and 'public health related methods of use or uses of any molecule or other substance, whatsoever used, for the prevention or treatment of any disease which the Minister responsible for health may designate as a serious health hazard or as a life threatening disease.'¹⁰⁵

- Zanzibar: specifically excludes 'new uses of known product or process'.¹⁰⁶ Interestingly, this Zanzibar provision to prevent evergreening pre-dates the EAC TRIPS Flexibilities Policy of 2013.

Additionally, as far as the criterion of novelty is concerned, all the countries in the study adopt the absolute novelty standard with the exception of Malawi,¹⁰⁷ Zimbabwe¹⁰⁸ and (surprisingly for its generally more liberal use of flexibilities) Zambia.¹⁰⁹

Recommendations

1. **Exclusions to patentability to cover naturally occurring substances even if extracted, isolated or purified, unless non-obvious changes are introduced that result in new and different properties. DNA and other genetic material should also be excluded since they are naturally occurring.**
2. **Novelty to be defined so as to include in the prior art disclosure by all means, whether specific or generic (e.g. in a Markush claim) anywhere in the world, covering all products and processes or information related to them).**
3. **Inventive step to be defined so as to exclude:**
 - a) **Secondary patents such as on new formulations, salts, polymorphs, dosages, simple combinations and other innovations that are the outcome of common knowledge or routine practices for the skilled person.**
 - b) **Use claims: the new pharmaceutical use for a product not previously used as such (as it is not novel) or the second pharmaceutical use discovered for a pharmaceutical product (as it is equivalent to a method of therapeutic treatment).**
4. **Industrial applicability to be defined to exclude those innovations that have no technical effect (such as abstract ideas) including therapeutic, surgical and diagnostic methods.**
5. **Disclosure to be sufficient to enable:**
 - a) **execution by an ordinary person skilled in the art, and**
 - b) **reproduction of each embodiment of the invention (so as to prevent excessively broad claims, such as Markush claims, as it is impossible to conduct a prior search for this type of claim and there is generally no evidence about the functional equivalence of the claimed elements).**

iii) Patent Examination

Examination of patent applications can occur in three ways:¹¹⁰

1. **Formality examination only—patent applications are decided purely on formal requirements being satisfied (completion of required forms, declarations and payment of necessary fees).**

¹⁰⁵ Section 17 (c), (e), (f) and (h) respectively of the Patents Act No 40 of 2016.

¹⁰⁶ Section 3(1)(v) Industrial Property Act No 4 of 2008.

¹⁰⁷ Section 2 Patents Act (Chapter 49:02) (1958).

¹⁰⁸ Section 2(2)(a) The Patents Act [Chapter 26:03] (amended by Act 9 of 2002).

¹⁰⁹ Section 2 read with section 18 of the Patents Act, 2016 (Act No. 40 of 2016).

¹¹⁰ WIPO, *Alternatives in Patent Search and Examination*. Policy Guide (2014), 6-9.

https://www.wipo.int/edocs/pubdocs/en/wipo_pub_guide_patentsearch.pdf (WIPO Policy Guide 2014).

2. Formality examination and prior art search—after the formality requirements are met and a search report of a prior art search establishes the novelty of the invention in terms of the applicable national law, a patent is granted without substantive examination.
3. Formality examination, prior art search and substantive examination (SSE)—once the formality requirements have been met, the examiner conducts a prior art search and substantive examination, which is meant to establish whether the requirements of novelty, inventive step and industrial applicability have been met.

Options 1 and 2 are preferred as cost-saving systems for patent offices as they do not require the employment of specialist patent examiners. These perceived cost savings, however, are offset by the cost to the public of unexamined and, possibly, unworthy patents. From the perspective of access to medicines, the SSE route is preferable, as the result would be the grant of fewer undeserving patents, thereby enabling generic competition and more affordable medicines.

Only a few countries in Africa conduct SSE of patents, due to resource constraints.¹¹¹ This is apparent despite the provisions in the legislation of many of them for such examination (refer to Table 2). A case in point is Tanzania.¹¹² Uganda, on the other hand, has adopted a regime in which not all patents are examined as to their substance, but the relevant authority (in this case, the Minister) has the authority to designate that a particular type of patent application shall be subject to examination.¹¹³

The majority of African countries are Members of one of the two major regional IP frameworks, namely, ARIPO and OAPI, which facilitate the filing of a single application in order to obtain protection in several territories. In the case of ARIPO, countries retain their own national laws, so that patent protection may be obtained either by direct filing in those countries, or through designation in an ARIPO patent application. With the exception of one country, more than 94% of patent applications are filed in Member States through designation in an ARIPO patent application as opposed to national filing.¹¹⁴ The outlier in this regard is Kenya, which, since the beginning of the last decade, has been processing an increasing number of patents in its national office, peaking in 2009 when some 37% of its patents were granted by the national office, according to available data.¹¹⁵ South Africa, which is not a Member of ARIPO, processes its own patent applications through the Companies and Intellectual Property Commission on the basis of the satisfaction of formal requirements, with no substantive examination as to the merits.¹¹⁶

Patent protection in the OAPI Member States is obtained exclusively through the OAPI offices, and applicable to all 17 of its Member States. The applications are examined as to form only, although substantive examination is envisaged in terms of the revised IP Law of OAPI (Bangui Agreement).¹¹⁷

¹¹¹ Kisch IP, *South Africa: African Patent Options: Roads Less Travelled*

<http://www.mondaq.com/southafrica/x/836720/Patent/African+patent+options+Roads+less+travelled> (Kisch IP).

¹¹² SJ Mwakaje, *National Study in Intellectual Property and Small and Medium Sized Enterprises in Tanzania* (2011) https://www.wipo.int/edocs/pubdocs/en/wipo_natstudy_sme_tanzania.pdf.

¹¹³ Section 31 of the Uganda Industrial Property Act, 2014.

¹¹⁴ Kisch IP.

¹¹⁵ iHub Kenya, *Patenting in Kenya* (undated)

https://files.ihub.co.ke/ihubresearch/uploads/2012/november/1352902636_819_482.pdf (iHub).

¹¹⁶ Department of Trade and Industry, South Africa, *Companies and Intellectual Property Commission* <http://www.cipc.co.za/za/> (CIPC).

¹¹⁷ Kisch IP.

Recommendations

1. **Examining offices should adopt detailed examination guidelines to rigorously apply the patentability criteria (so as to ease the burden on resource-strapped offices, by enabling them to reject unmerited applications).**
2. **Regional IP offices, ARIPO and OAPI, should adopt similarly rigorous examination guidelines.**

iv) *Pre-Grant Opposition*

Opposition to the application for, or grant of, a patent is a flexibility present in many jurisdictions. It usually entails a party opposing the grant of a patent to give notice and allege the grounds on which the opposition is based. It may be utilised either before or after the grant of a patent, or provisions may be inserted for both forms of opposition.¹¹⁸ The legality of administrative opposition procedures is addressed in Article 62 of the TRIPS Agreement to the effect that where a Member State's laws provide for such procedures: 'administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41.'¹¹⁹ Additionally, final administrative decisions shall be subject to review by a judicial or quasi-judicial authority.¹²⁰ This allows third parties to intervene during the patent application process, in order to challenge the granting of a patent on any number of acceptable grounds, including failure to comply with the requirements of country's legislation.

The legislation of the following African countries contains provisions for pre-grant opposition:

- **Malawi:** Any interested party, including the Government, may oppose within 3 months of publication of the acceptance of a complete specification, or such period as the Registrar may allow on application, or, with the consent of the applicant, at any time before the sealing of the patent, on 13 specified grounds and no other. which grounds include the applicant's lack of standing, being in fraud of the rights of the opposer or based on a material misrepresentation, as well as the lack of proper disclosure, or meeting the requirements of novelty, inventive step and industrial applicability.¹²¹ The section further elaborates the process for and disposition of the application to oppose.¹²²
- **Zimbabwe:** The provisions in this legislation¹²³ are almost identical to those in the Malawi Patents Act.
- **Zambia:** Here the provisions are substantially similar to those of Malawi, with the difference being that the consent of the patent applicant is not required for the opposition to be brought before the sealing of the patent. Here again, opposition must be on one of 19 grounds (similar to the Malawi provision) in a closed list.¹²⁴ The ensuing section further elaborates the process for and disposition of the application to oppose.¹²⁵
- **Mozambique:** Here, in contrast to the preceding three countries, the entitlement of a the person to oppose the grant of the patent is qualified by the clause "would be

¹¹⁸ WIPO, *Opposition Systems* https://www.wipo.int/scp/en/revocation_mechanisms/opposition/index.html (WIPO Opposition Systems).

¹¹⁹ Article 62.4 of the TRIPS Agreement. The principles referred to in Article 41.2 and 41.3 speak to fair and equitable procedures, not being unnecessarily complicated or costly or entail unreasonable time limits or unwarranted delays; decisions to preferably be in writing and reasoned, based on evidence in respect of which parties were given the opportunity to be heard; and made available to the parties without undue delay.

¹²⁰ Article 62.5 of the TRIPS Agreement.

¹²¹ Section 22(1) Patents Act (Chapter 49:02) (1958).

¹²² Section 22(2) to 22(9) Patents Act (Chapter 49:02) (1958).

¹²³ Section 17(1) to (10) Patents Act (Chapter 26:03, as amended up to Act No 14 of 2002).

¹²⁴ Section 56 The Patents Act, 2016 (Act No. 40 of 2016).

¹²⁵ Section 57 The Patents Act, 2016 (Act No. 40 of 2016).

prejudicial to him”¹²⁶ thus limiting the category of persons who have standing to oppose. In the absence of a definition of “prejudice” the term could be interpreted so narrowly as to exclude any person who acts in the public interest from bringing an application to oppose. In addition, it may constitute a further hurdle in terms of what grounds of opposition may be sustained.

- Botswana: Here, any “interested person” is permitted to submit to the Registrar of Patents, an observation on or objection to the application for a patent, on the grounds that the claimed subject matter does not constitute an invention or is otherwise excluded from patentability, or that various other requirements have not been complied with.¹²⁷ The ensuing sub-sections deal with the process and disposition of the opposition.¹²⁸ Any party submitting an observation or objection who is aggrieved by any decision of the Registrar, may apply to the High Court for recourse, and the Registrar shall suspend the patent application pending the decision of the court.¹²⁹
- Burundi: Here, any person may file an opposition, indicating the arguments and evidence in support of the opposition, and must pay the prescribed fee.¹³⁰ The applicable grounds for an opposition have not been specified. The Act requires the Industrial Property Director to hear both the patent applicant and opposing party before making a decision.¹³¹
- Liberia: Any interested party may file a notice of opposition, including the grounds for opposition and all relevant evidence, after publication of the application for a patent to the Director General.¹³² The ensuing sub-paragraphs provide for the process and hearing of the opposition.¹³³
- Uganda: Any interested party may file a notice of opposition after publication of the patent application, setting out the grounds for opposition (the failure to meet the formal or substantive conditions of patentability) and all relevant evidence.¹³⁴ The ensuing sub-sections deal with the procedure and, if the registrar deems necessary, the hearing of the objection.¹³⁵
- Zanzibar: Any interested party may file a notice of opposition after publication of the patent application, setting out the grounds for opposition (including failure to meet the formal and substantive conditions of patentability) and relevant evidence.¹³⁶ The ensuing sub-paragraphs deal with the procedure and, if the registrar deems necessary, the hearing of the objection.¹³⁷

The remaining study countries do not have any provision for pre-grant opposition, although the legislation of Sao Tome and Principe does cater for an objection to be raised by the patent office but not the general public.¹³⁸

Evidence of the actual use of the pre-grant opposition mechanism is scant due, no doubt in part, to the fact that the majority of the study countries are Members of ARIPO, which does not have any provision for such opposition and that the majority of applications are those processed through the ARIPO filing mechanism.¹³⁹ The same report (Shashikant 2014)

¹²⁶ Article 68(1) Industrial Property Code (approved by Decree No 47/2015 of December 31, 2015).

¹²⁷ Section 21(5) Industrial Property Act No 8 of 2010.

¹²⁸ Section 21(6) to (10) Botswana Industrial Property Act No 8 of 2010.

¹²⁹ Section 21(11) of the Botswana Industrial Property Act.

¹³⁰ Article 48 Law No 1/13 of July 28, 2009, relating to Industrial Property in Burundi (Burundi Industrial Property Law).

¹³¹ Article 49 Law No 1/13 of July 28, 2009, relating to Industrial Property in Burundi (Burundi Industrial Property Law).

¹³² Section 13.9(k) Intellectual Property Act, 2016.

¹³³ Section 13.9(l) to (n) of the Liberia Intellectual Property Act.

¹³⁴ Section 28(7) and (8) The Industrial Property Act, 2014.

¹³⁵ Section 28(10) to (12) The Industrial Property Act, 2014.

¹³⁶ Section 10(7)(a) Industrial Property Act No 4 of 2008.

¹³⁷ Section 10(7)(b) to (d) Industrial Property Act No 4 of 2008.

¹³⁸ Article 78.3 of the Intellectual Property Code (approved by Decree-Law No. 23/2016).

¹³⁹ See Shashikant (2014), 38-40.

recommends that Member States 'with pre-grant opposition procedures in their national legislations should work to operationalizing such procedures with regard to patent applications processed by the ARIPO Office.'¹⁴⁰

As a result, African countries have enjoyed nowhere near the success in filing patent oppositions as Brazil, India and Thailand.¹⁴¹

Recommendations

- 1. Opposition guidelines to be adopted to enable an effective administrative process, allowing legal standing to any person, especially one acting in the public interest, and to provide for opposition on any grounds relating to patentability requirements.**
- 2. Similar guidelines to be adopted for examination by the ARIPO and OAPI offices.**

¹⁴⁰ Shashikant (2014), 64.

¹⁴¹ See, for example, MSF. *MSF launches online resource for challenging unwarranted drug patents* (2012) <https://www.msfaccess.org/msf-launches-online-resource-challenging-unwarranted-drug-patents> (MSF 2012)

Table 2: Patent Law in Africa Related to Pre-grant Flexibilities

STATE	Patentability of Pharmaceuticals	Patentability Criteria	Patent Examination	Pre-Grant Opposition
Angola	Excludes pharmaceuticals	Absolute novelty	N/A	N/A
Botswana	Pharmaceuticals patentable but may be excluded	Complies with Article 27.1 Absolute novelty	Substantive	Any interested party may submit an application to 'observe' or oppose.
Burundi	Pharmaceuticals were excluded until 1 January 2016.	Complies with Article 27.1 Absolute novelty	Formal	Any interested party may oppose grant.
Comoros	Pharmaceuticals patentable	Complies with Article 27.1 Absolute novelty	Formal	N/A
DRC	Pharmaceuticals patentable	Absolute novelty	N/A	N/A
Gambia	Pharmaceuticals patentable	Complies with Article 27.1 Absolute novelty	Formal	N/A
Ghana	Pharmaceuticals patentable	Complies with Article 27.1 Absolute novelty	Substantive	N/A
Kenya	Pharmaceuticals patentable	Absolute novelty	Substantive	N/A
Lesotho	Pharmaceuticals patentable	Complies with Article 27.1 Absolute novelty	Substantive	N/A
Liberia	Excludes pharmaceutical products until January 1, 2016, or until the expiry of such a later period of extension agreed upon by the WTO for LDCs	Complies with Article 27.1 Absolute novelty	Substantive	Any interested party may oppose grant.
Madagascar	Excludes pharmaceuticals from patentability	Complies with Article 27.1 Absolute novelty	Substantive	N/A
Malawi	Pharmaceuticals patentable	Relative novelty	Substantive	Any interested party, including the State, may oppose grant.
Mauritius	Pharmaceuticals patentable	Absolute novelty	Formal	N/A
Mozambique	Pharmaceuticals protected	Absolute novelty	Substantive	Any party who feels the granting of a patent would be prejudicial to them may

				oppose grant.
Namibia	Pharmaceutical patentable	Absolute novelty	Substantive	N/A
Rwanda	Exclusion of pharmaceutical products, for the purposes of international conventions to which Rwanda is party	Absolute novelty	Substantive	N/A
Sao Tome and Principe	Pharmaceuticals patentable	Absolute novelty	Substantive	N/A
Seychelles	Pharmaceuticals patentable	Absolute novelty	Formal	N/A
Sierra Leone	Pharmaceuticals patentable	Absolute novelty	Substantive	N/A
South Africa	Pharmaceuticals patentable	Complies with Article 27.1 Absolute novelty	Formal	N/A
South Sudan	Pharmaceuticals patentable	Complies with Article 27.1 Absolute novelty	Formal	N/A
(North) Sudan	Pharmaceuticals patentable	Complies with Article 27.1 Absolute novelty	Formal	N/A
eSwatini	Pharmaceuticals patentable	Complies with Article 27.1 Absolute novelty	Substantive	N/A
Tanzania	Pharmaceuticals patentable	Absolute novelty	Unclear. Act provides that regulations may provide for substantive examination; however, no evidence that any regulations have been promulgated to implement this.	N/A
Uganda	Excludes pharmaceuticals	Complies with Article 27.1 Absolute novelty	Act provides for formal and the Minister may	Any interested party may oppose grant.

			direct for substantive examination.	
Zambia	Pharmaceuticals patentable	Relative novelty	Substantive	Any interested party, including the state, may oppose grant.
Zanzibar	Excludes pharmaceutical products and processes until 1 January 1, 2016 or the expiry of such later period of extension agreed upon by the WTO Council for TRIPS	Absolute novelty	Substantive examination	Any interested party may oppose grant
Zimbabwe	Pharmaceuticals patentable	Complies with Article 27.1 Relative novelty	Formal	Any interested party, including the state, may oppose grant

b) Post-Grant Flexibilities

i) Patent Terms

A basic tenet of patent law is that the state, in return for public disclosure of the invention, gives the inventor a time-limited monopoly to exploit that invention. The patent secures for its holder the right to exclude others from using the invention and thereby delays competition. The length of a patent term is thus relevant to the entry of competition by the manufacturers of generics, which is essential to driving down prices. Shorter patent terms, in the absence of utilising other flexibilities, such as the LDC transition provision, are one mechanism by which States can promote access to healthcare.

Not all LDCs have taken advantage of the LDC transition provision to reduce the duration of the patent term in their territories.

Eight LDCs and four non-WTO Members provide patent protection for a minimum of 20 years. The LDCs are Burundi,¹⁴² Comoros,¹⁴³ Liberia,¹⁴⁴ Mozambique,¹⁴⁵ Rwanda,¹⁴⁶ Sierra Leone,¹⁴⁷ Uganda¹⁴⁸ and Zambia.¹⁴⁹ The non-WTO States are Sao Tome and Principe,¹⁵⁰ North and South Sudan¹⁵¹ and Zanzibar.¹⁵²

Seven LDCs provide protection for less than 20 years. Those providing a minimum of 15 years are Angola,¹⁵³ the DRC¹⁵⁴ (for drugs only), Gambia,¹⁵⁵ Lesotho¹⁵⁶ and Madagascar.¹⁵⁷ Malawi¹⁵⁸ provides for 16 years and Tanzania¹⁵⁹ for 10 years. Both Madagascar and Tanzania permit an additional 5 years on a motivated request by the patent holder.

Recommendations

- 1. LDCs to review and remove patent protection for pharmaceuticals, even if granted for reduced periods, as they are not required to provide for any protection on account of the LDC transition provision. If patents are granted, a reduced term will accelerate the market entry of generic medicines.**
- 2. Non-LDCs not to agree, in trade negotiations or otherwise, to patent term extensions for any reason whatsoever.**

ii) Bolar Exception

The regulatory review exception—also known as the ‘Bolar’ or ‘early working’ exception—refers to provisions that allow for the use of a patented invention in order to comply with regulatory requirements for market approval for a generic product before the expiry of the

¹⁴² Article 62 Law No 1/13 of July 28, 2009

¹⁴³ Article 36 Loi du 5 juillet 1844 sur les brevets d'invention

¹⁴⁴ Section 13.12 Liberia Intellectual Property Act, 2016.

¹⁴⁵ Article 73 Industrial Property Code (approved by Decree No. 47/2015 of December 31, 2015)

¹⁴⁶ Article 42 Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property.

¹⁴⁷ Section 24 Patents and Industrial Design Act, 2012 (Act No. 10 of 2012).

¹⁴⁸ Section 46 Industrial Property Act, 2014.

¹⁴⁹ Section 65(3) Patents Act, 2016 (Act No. 40 of 2016)

¹⁵⁰ Article 103 Intellectual Property Code (approved by Decree-Law No. 23/2016).

¹⁵¹ Section 25 Patent Law No. 58 of 1971.

¹⁵² Section 13(1)(a) Zanzibar Industrial Property Act, 2008 (Act No. 4 of 2008).

¹⁵³ Article 6 Law No 3/92 of February 28, 1992.

¹⁵⁴ Article 36 Law No. 82-001 of January 7, 1982.

¹⁵⁵ Article 13(1) Industrial Property Act (Cap. 95:03).

¹⁵⁶ Section 14 Industrial Property Order, 1989 (Order No. 5 of 1989, as last amended by Act No. 4 of 1997)

¹⁵⁷ Section 1.10 Ordinance No. 89-019 Establishing Arrangements for the Protection of Industrial Property in Madagascar (of July 31, 1989).

¹⁵⁸ Section 29 of the Patents Act (Chapter 49:02).

¹⁵⁹ Section 39(1) and (2) of the Patents (Registration) Act, Cap 217.

relevant patent. This exception enables generic manufacturers to prepare for eventual entry into the local and/or foreign markets (e.g. other African countries) through the production of first batches for review prior to market approval and ensures that generic versions could be marketed as soon as the patent on a medicine expires.

Over 40% (12) of the study countries contain this provision in their legislation. They are Botswana,¹⁶⁰ Kenya,¹⁶¹ Liberia,¹⁶² Namibia,¹⁶³ Rwanda,¹⁶⁴ Sao Tome and Principe¹⁶⁵ Seychelles,¹⁶⁶ South Africa,¹⁶⁷ Uganda,¹⁶⁸ Zambia,¹⁶⁹ Zanzibar¹⁷⁰ and Zimbabwe.¹⁷¹

No examples of actual use of this flexibility could be found for the study countries.

Recommendation

The exception for regulatory approval to be permitted for both domestic and export requirements.

iii) Compulsory Licensing and Government Use

A compulsory licence is an authorisation granted by a government allowing third parties to produce a patented product or to utilise a patented process without the consent of the patent holder. In a similar vein, 'government use' or 'crown use' is an authorisation by the government, to itself or other entities or contractees acting on behalf of the government, to make use of a patented product or process without the consent of the patent holder. In both instances, a royalty is required to be paid to the patent holder.¹⁷²

The availability and use of compulsory licensing in the pharmaceutical sector were apparently limited during the early twentieth century, as many countries excluded such products from patentability.¹⁷³ It has come to be increasingly used in industrialised countries such as Canada, the US and the UK. Recently, during the 2001 anthrax scare, Canada and the US were willing to consider invoking this flexibility, as Italy has done on a number of occasions on anti-trust grounds.¹⁷⁴ A large number of compulsory licenses have been issued in the USA for government use and to address anti-competitive practices. Such licenses have recently been granted as well in relation to medicines in Russia and Germany.

Article 31 (a) to (l) of the TRIPS Agreement allows for the grant of compulsory licences provided certain conditions are satisfied and procedures followed. These include, among others: a prior unsuccessful attempt to obtain a voluntary licence from the right holder on reasonable commercial terms and within a reasonable period of time; limited scope and duration of the authorised use; non-exclusivity and non-assignability; use predominantly for the supply of the domestic market; payment of adequate remuneration to the patent holder; judicial review of the decision to license and the amount of remuneration; and the provision for a dependent patent. Some of these conditions are waived, for example, the prior

¹⁶⁰ Section 25(1)(f) Industrial Property Act, 2010 (Act No. 8 of 2010).

¹⁶¹ Section 54(2) Industrial Property Act No 3 of 2001.

¹⁶² Section 13.11(iv) of the Liberia Intellectual Property Act, 2016.

¹⁶³ Section 43(20) Industrial Property Act No 1 of 2012).

¹⁶⁴ Article 41 Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property.

¹⁶⁵ Article 105.1(c) Intellectual Property Code (approved by Decree-Law No. 23/2016).

¹⁶⁶ Section Industrial Property Act No 7 of 2014.

¹⁶⁷ Section 69A Patents Act No 57 of 1978.

¹⁶⁸ Section 44(a) of the Industrial Property Act, 2014.

¹⁶⁹ Section 75(1)(f) The Patents Act, 2016 (Act No. 40 of 2016).

¹⁷⁰ Section 11(4)(v) Industrial Property Act No. 4 of 2008.

¹⁷¹ Section 24B Patents Act [Chapter 26:03] (amended by Act 9 of 2002).

¹⁷² Article 31(h) of the TRIPS Agreement requires the payment of 'adequate remuneration'.

¹⁷³ 't Hoen (2009), 40.

¹⁷⁴ 't Hoen (2009), 41-42.

negotiation requirement (in cases of emergency and public non-commercial use, or to remedy anti-competitive practices) or the domestic use requirement (in instances of anti-competitive practices).

Article 31 of the TRIPS Agreement does not specify or otherwise limit the grounds upon which licences can be granted. This clarification was one of the key outcomes of the Doha Declaration, namely that each country has the right to grant compulsory licences, to determine the grounds on which to grant them and to determine what constitutes an emergency or other circumstances of extreme urgency, notably public health crises, with no restrictions as to disease coverage or frequency of use. Another eventual outcome—waiver of the domestic use requirement in respect of countries with insufficient or no manufacturing capacity—has now been codified in Article 31*bis*. Finally, the Declaration reiterated the freedom of countries to adopt the exhaustion regime of their choice (in order to facilitate parallel importation).

In the wake of the HIV/AIDS pandemic and buoyed by the Doha Declaration's pro-public health interpretation of the TRIPS Agreement, a significant number of developing countries and LDCs afflicted by this crisis issued a combination of compulsory licences and government use orders to facilitate the acquisition of ARVs and, occasionally, medicines for other conditions. Such countries include Brazil, Ecuador, Eritrea, Ghana, India, Indonesia, Malaysia, Mozambique, Thailand, Zambia, Zimbabwe¹⁷⁵ and others as elaborated below.

Compulsory licences are generally available on a variety of grounds, most notably in relation to patents where the patentee is found to have abused its rights in one manner or another, for example, by excessive pricing, refusals to license or failure to work but also where the government wants to ensure alternate sources of medicines, to facilitate co-formulations or even to promote local production. Countries might also consider including judicial licences as an alternative remedy to interdicts in claims of infringement.¹⁷⁶ The grant of a compulsory or government use licence thus constitutes a proactive governmental intervention when market forces result in a disequilibrium between the objectives of rewarding innovation and ensuring social and economic welfare.¹⁷⁷ They 'ensure an efficient operation of innovation markets by avoiding the risk that patents themselves become barriers to invention and innovation ... (and) ... (a)s policy tools, compulsory licences help to ensure that patent protection remains properly balanced with other socio-economic interests.'¹⁷⁸

Historically, African countries inherited colonial legislation, which included the 'traditional' grounds on which licences could be sought. These typically included insufficiency of exploitation of the invention, inability to meet demand, refusal to grant a licence on reasonable terms or in order to remedy anti-competitive practices and dependent patents.

African countries have increasingly become cognisant of the impacts of patents on the pricing of medicines and the potentially deleterious effect on the quality of and right to accessible health care. The existing framework with regard to licences proved inadequate to meet the new challenges of epidemics such as HIV/AIDS, and after the Doha Declaration, African countries elected to introduce more public health-friendly provisions. As a result, the following countries all expressly grant compulsory and government use licences, referencing

¹⁷⁵ See M Khor, *Compulsory License and "Government Use" to Promote Access to Medicines: Some Examples*. Third World Network (2014), 24 (Khor 2014).

¹⁷⁶ See, for example, UNDP, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition, and Medicines Law* (2013), 39 https://www.undp.org/content/dam/undp/library/hivaids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf (UNDP 2013).

¹⁷⁷ For a history of the evolution of intellectual property, compulsory licences and related issues, see C May and SK Sell, *Intellectual property rights: a critical history*, Lynne Rienner Publishers (2006).

¹⁷⁸ Max Planck Institute, *Declaration on Patent Protection: Regulatory Sovereignty under TRIPS* (2014) p 9 <https://www.mpg.de/8133454/Patent-Declaration1.pdf> (Max Planck Institute 2014).

the necessity to protect public health: Botswana,¹⁷⁹ Burundi,¹⁸⁰ Liberia¹⁸¹, Mozambique,¹⁸² Mauritius,¹⁸³ Namibia,¹⁸⁴ the Seychelles,¹⁸⁵ eSwatini,¹⁸⁶ Tanzania,¹⁸⁷ Zambia¹⁸⁸ and Zanzibar¹⁸⁹ The ground for granting these licences, related to 'health' or 'emergency', is also referenced in the legislation of Angola,¹⁹⁰ Ghana,¹⁹¹ Kenya,¹⁹² Malawi,¹⁹³ Rwanda,¹⁹⁴ Sierra Leone,¹⁹⁵ Sudan,¹⁹⁶ Uganda¹⁹⁷ and Zimbabwe.¹⁹⁸

A number of countries' legislation permits compulsory or government use licences where vital sectors of the economy, including health, are affected. The earliest of these in the study countries is to be found in Tanzania's Patents Act, 1987, which reads:

'Compulsory licences for products and processes of vital importance

- (1) The Minister may, by order published in the *Gazette*, direct that, for a patented invention concerning a certain kind of product, or a process for the manufacture of such a product, declared in the order to be of vital importance for the defence or for the economy or for public health, a compulsory licence may be granted.
- (2) A compulsory licence with respect to any product or process specified in the order referred to in subsection (1) may be requested at any time after the grant of the relevant patent, in court proceedings instituted against or by the owner of the said patent.¹⁹⁹

This is an interesting use of a Ministerial declaration or statutory instrument combined with a court-ordered licence. Sub-section (1) provides the enabling provision for licensing. Thereafter, in sub-section (2) a party may request a judicial licence on the back of the declaration.

A similar provision is to be found in Angola's legislation:

'(Deprivation of a patent)

Where the public interest, in particular the interests of national security, health or the development of vital sectors of the national economy, so require it, the Council of Ministers may decide that an invention should be exploited by a State body or by a

¹⁷⁹ Section 31(a) Industrial Property Act, 2010 (Act No. 8 of 2010).

¹⁸⁰ Article 78 Industrial Property Law, No. 1 of 2009.

¹⁸¹ Article 13(3) Liberia Intellectual Property Act, 2016.

¹⁸² Article 92.2 Industrial Property Code (approved by Decree No. 47/2015 of December 31, 2015).

¹⁸³ Section 25(1)(a) Patents, Industrial Designs and Trademarks Act 2002.

¹⁸⁴ Section 57 Industrial Property Act, 2012 (Act No. 1 of 2012).

¹⁸⁵ Section 23 Industrial Property Act 2014 (Act No. 7 of 2014).

¹⁸⁶ Section 12(6)(a) Industrial Property Law, No. 6 of 1997.

¹⁸⁷ Section 55(1) Patents Act, 1987.

¹⁸⁸ Section 99(1)(e) The Patents Act, 2016 (Act No. 40 of 2016).

¹⁸⁹ Section 14.1(a) Industrial Property Act No. 4 of 2008.

¹⁹⁰ Article 10 Industrial Property Law, No. 3 of 1992

¹⁹¹ Section 13 Patents Act, 2003 (Act 657).

¹⁹² Section 1(c) Industrial Property Act, (Act No. 3 of 2001 as amended up to Act No. 11 of 2017).

¹⁹³ Section 14 Patents Act (Chapter 49:02) (1958).

¹⁹⁴ Article 52 Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property.

¹⁹⁵ Section 26(1) The Patents and Industrial Design Act, 2012.

¹⁹⁶ Section 35 Patent Law No. 58 of 1971.

¹⁹⁷ Section 66(1)(a) The Industrial Property Act, 2014. Uganda has also adopted the TRIPS Article 31*bis* flexibility, enabling it to export up to 100% of medicines produced (Section 44(e) of the Industrial Property Act, 2014). Additionally, its laws provide for the authorisation of a compulsory licence as a remedy to anti-competitive conduct (Section 66.1(b) of the Industrial Property Act, 2014).

¹⁹⁸ Section 35 The Patents Act [Chapter 26:03] (amended by Act 9 of 2002).

¹⁹⁹ Section 55 Patents Act, 1987.

third party designated by the relevant supervisory minister, without the consent of the patent holder, in return for payment of fair compensation.²⁰⁰

The Angolan provision is distinct in that it relates to government use. Furthermore, the term 'deprivation' appears to refer to the patent holders being deprived of their exclusive exploitation of the relevant invention and not of their full proprietary rights.

Both these provisions pre-date the TRIPS Agreement and can be regarded as pre-TRIPS flexibilities. A similar type of provision may be found in the post-TRIPS legislation of Mauritius,²⁰¹ Namibia,²⁰² Sierra Leone,²⁰³ Uganda,²⁰⁴ Zambia²⁰⁵ and Zanzibar.²⁰⁶

While most compulsory or government use licences require the applicant to establish clear grounds in the application, there are some notable exceptions, in the form of presumptive licences based on a similar premise to that of a 'vital' sector or a 'necessity'. A notable example is that of Malawi, with the Patents Act (Chapter 49:02) 1958 providing for a presumption in favour of granting compulsory licences, which have been applied for²⁰⁷—a provision designed to secure, in this instance, access to medicines to the public.²⁰⁸ Similar provisions are found in the legislation of Zimbabwe²⁰⁹ and Tanzania.²¹⁰ Zimbabwe is the only country that appears to have used this flexibility, and its government use licence invoke the following legal provisions:²¹¹

1. Section 34 of the Patents Act—enabling provision for the government use licence (Use of patented inventions for service of the state).
2. Section 35 of the Patents Act—enables the declaration of an emergency to override, in this case, antiretroviral patents (Special provisions as to state use during emergency).
3. General Notice 240 of 2002—declaration of period of emergency for an initial period of six months commencing 24 May 2002 .
4. Statutory Instrument 32 of 2003—extending the period of emergency for a further five years (from January 2003 to December 2008).

The TRIPS Flexibilities Database has records of 26 instances where the Article 31 flexibility has been invoked, in some 14 African countries, with the overwhelming majority of them resulting in voluntary licences.²¹² In the case of Cameroon, it was not executed for lack of a response. In South Africa, competition law was utilised to force pharmaceutical companies to negotiate voluntary licences when the threat of compulsory licences loomed.²¹³

Recommendations

- 1. Countries to include the maximum possible complement of public health-oriented grounds for compulsory and government use licences, as outlined above.**

²⁰⁰ Article Law No 3/92 of February 28, 1992.

²⁰¹ Section 25(1)(a) Patents, Industrial Designs and Trademarks Act 2002.

²⁰² Section 57 Industrial Property Act, 2012 (Act No. 1 of 2012).

²⁰³ Section 26 Patents and Industrial Design Act No 10 of 2012.

²⁰⁴ Section 66 Industrial Property Act, 2014.

²⁰⁵ Section 99(1)(e) The Patents Act, 2016 (Act No. 40 of 2016).

²⁰⁶ Section 14 Industrial Property Act No. 4 of 2008.

²⁰⁷ Section 38(1) Patents Act (Chapter 49:02) 1958.

²⁰⁸ Section 38(2) Patents Act (Chapter 49:02) 1958.

²⁰⁹ Section 32 Patents Act (Chapter 26:03, as amended up to Act No 14/2002).

²¹⁰ Section 55 Patents Act, 1987.

²¹¹ Sections 34 and 25 The Patents Act [Chapter 26:03] (amended by Act 9 of 2002), read with General Notice 240 of 2002 and Statutory Instrument 32 of 2003.

²¹² See TRIPS Flexibilities Database.

²¹³ See note 283, and accompanying text, below.

- 2. Adopt easy-to-use remuneration guidelines for compulsory licenses appropriate to a country's level of development.**
- 3. Adopt expeditious administrative processes and procedures for applications and the grant of compulsory licenses, including that appeals against a decision granting a compulsory license should not suspend the execution of the latter.**

iv) *Research Exception*

The premise underlying the publication of patents is to allow for the dissemination of information in order to promote the research and development necessary for innovation, yet extending the scope of patent rights to the use of patented subject matter for research purposes can limit research and development. In the case of pharmaceuticals, this delays the availability of potentially life-saving drugs until after the term of a patent expires. Such an exception is permissible under Article 30 of the TRIPS Agreement and widely in use for both commercial and non-commercial purposes.

Twenty of the States examined in this study exempt research activities from the scope of patent rights; these include Botswana,²¹⁴ Burundi,²¹⁵ the DRC,²¹⁶ Ghana,²¹⁷ Kenya,²¹⁸ Lesotho,²¹⁹ Liberia,²²⁰ Mauritius,²²¹ Mozambique,²²² Namibia,²²³ Rwanda,²²⁴ Sao Tome and Principe,²²⁵ the Seychelles,²²⁶ Sierra Leone,²²⁷ South Sudan,²²⁸ (North) Sudan,²²⁹ Tanzania,²³⁰ Uganda,²³¹ Zambia²³² and Zanzibar.²³³

All countries should incorporate this flexibility into their legislation in order to support research in innovation, without the risk of claims for infringement. Other important exceptions relate to the production of medicines by pharmacies for individual use, and prior or private non-commercial use of a patented invention.

Recommendations

- 1. Countries to provide for research rights for commercial and non-commercial purposes and experimental and educational reasons.**
- 2. Countries to include other exceptions such as for formulation at pharmacies for individuals, prior use (before the patent grant) and private non-commercial use.**

v) *Parallel Imports*

²¹⁴ Section 25(1)(i) Industrial Property Act, 2010 (Act No. 8 of 2010).

²¹⁵ Article 56(3) Industrial Property Law, No. 1 of 2009.

²¹⁶ Section 11(4)(c) Law No. 82-001, January 1982.

²¹⁷ Section 10(4)(c) Patents Act, 2003 (Act 657).

²¹⁸ Section 58 Industrial Property Act, (Act No. 3 of 2001 as amended up to Act No. 11 of 2017).

²¹⁹ Section 13(3)(c) Industrial Property Amendment Act, 1997.

²²⁰ Article 12.6(d)(iv) Liberia Intellectual Property Act, 2016.

²²¹ Section 21(4)(d) Patents, Industrial Designs and Trademarks Act 2002.

²²² Article 75(a) Industrial Property Code (approved by Decree No. 47/2015 of December 31, 2015).

²²³ Section 43(1)(c) Industrial Property Act, 2012 (Act No. 1 of 2012).

²²⁴ Article 41(2) Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property.

²²⁵ Article 8(4)(c) Industrial Property Code Decree-Law No. 23/2016.

²²⁶ Section 60(1)(a) Industrial Property Act 2014 (Act No. 7 of 2014).

²²⁷ Section 23(1)(c) The Patents and Industrial Design Act, 2012.

²²⁸ Section 23(1) Patent Law No. 58 of 1971.

²²⁹ Section 23(1) Patent Law No. 58 of 1971.

²³⁰ Section 38 Patents Act, 1987.

²³¹ Section 43(1) The Industrial Property Act, 2014.

²³² Section 75(1)(a) The Patents Act, 2016 (Act No. 40 of 2016).

²³³ Section 12.4 (a) (iii) Industrial Property Act No. 4 of 2008

Parallel importation refers to the practice of ‘comparison-shopping’ in other countries to secure a patented product at a favourable price. This flexibility is enabled by Article 6 of the TRIPS Agreement.²³⁴ This is based on the notion that once a product has been placed on the market and sold into commerce, the patent holder loses any proprietary rights to it. A country using this flexibility can elect to adopt a national, regional or international exhaustion regime and, if adopting the last, it will have the right to parallel importation.

This provision is usually framed in legislation as a limitation on the rights of the patent holder or an act of non-infringement. Several African countries have incorporated such a provision. Among the study countries, those supporting international exhaustion are Botswana,²³⁵ Burundi,²³⁶ Ghana,²³⁷ Kenya,²³⁸ Liberia,²³⁹ Namibia,²⁴⁰ Seychelles,²⁴¹ South Africa,²⁴² Sierra Leone,²⁴³ Zambia,²⁴⁴ Zanzibar²⁴⁵ and Zimbabwe.²⁴⁶

Madagascar,²⁴⁷ Mozambique,²⁴⁸ Rwanda,²⁴⁹ Sao Tome and Principe,²⁵⁰ South Sudan,²⁵¹ eSwatini²⁵² and Uganda²⁵³ allow for national exhaustion.

In both Malawi and Namibia, the importing of patented products is subject to the state first authorising some form of limitation of the patent-holder’s rights, either by declaring a state of emergency²⁵⁴ or granting a government use²⁵⁵ or compulsory²⁵⁶ licence.

Kenya is a particularly exceptional case. Its parallel importation provisions are based on a broad interpretation of the exhaustion doctrine, permitting even the importation of legitimately produced and marketed generic medicines.²⁵⁷ The relevant provision previously read:

‘The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.’²⁵⁸

To counter the charge that this would open the way to trade in pirated or otherwise illegal products, the regulatory authorities promulgated the following provision:

²³⁴ Article 6 of the TRIPS Agreement reads: ‘For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.’

²³⁵ Section 25(1)(a) Industrial Property Act, 2010 (Act No. 8 of 2010).

²³⁶ Article 57 Industrial Property Law, No. 1 of 2009.

²³⁷ Section 11(4)(a) Patents Act, 2003 (Act 657).

²³⁸ Section 58(2) Industrial Property Act, (Act No. 3 of 2001 as amended up to Act No. 11 of 2017).

²³⁹ Section 13.11(b) Liberia Intellectual Property Act, 2016.

²⁴⁰ Section 42(1)(a) Industrial Property Act, 2012 (Act No. 1 of 2012).

²⁴¹ Section 19 The Patents and Industrial Design Act, 2012.

²⁴² Section 45(2) Patents Act No 57 of 1978.

²⁴³ Section 23(1)(a) The Patents and Industrial Design Act, 2012.

²⁴⁴ Section 76 The Patents Act, 2016 (Act No. 40 of 2016).

²⁴⁵ Section 11(4)(a)(i) Industrial Property Act No. 4 of 2008

²⁴⁶ Section 24A The Patents Act [Chapter 26:03] (amended by Act 9 of 2002).

²⁴⁷ Section 30(2) Ordinance No. 89-019 Establishing Arrangements for the Protection of Industrial Property in Madagascar (of July 31, 1989).

²⁴⁸ Article 75(b) Industrial Property Code (approved by Decree No. 47/2015 of December 31, 2015).

²⁴⁹ Article 40 Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property.

²⁵⁰ Article 107 Industrial Property Code Decree-Law No. 23/2016.

²⁵¹ Section 23(2) Patent Law No 58 of 1971.

²⁵² Section 12(4)(a) Industrial Property Law, No. 6 of 1997.

²⁵³ Section 43(2) The Industrial Property Act, 2014.

²⁵⁴ Section 40 (6) Patents Act (Chapter 49:02) 1958

²⁵⁵ Ibid

²⁵⁶ Section 43(1) Industrial Property Act, 2012 (Act No. 1 of 2012)

²⁵⁷ RL Lettington & P Munyi. *Willingness and Ability to Use TRIPS Flexibilities: Kenya case study* (September 2004) 6 DFID Health Systems Resource Centre UK (Lettington & Munyi 2004).

²⁵⁸ Section 58.2 Industrial Property Act 2001 (Kenya Industrial Property Act).

'The limitation on the rights under a patent in section 58(2) of the Act extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market.'²⁵⁹

As a result, parallel importation of generic medicines, including ARVs, began in Kenya in 2002 with both NGOs and the public sector taking advantage of the flexibility provided in domestic legislation.²⁶⁰

The continued use of this flexibility, however, may be in jeopardy as a result of the 2008 decision in *Pfizer Inc. v. Cosmos Limited*,²⁶¹ which found Cosmos to have infringed Pfizer's patent on a broad spectrum antibiotic under the trademark 'Zithrox'. The Tribunal rejected a defence based on section 58(2) noting that 'the section does not give a blanket protection to third parties to exploit the patented invention.'²⁶²

The relevant section has subsequently been amended, evidently to accommodate the effect of this judgment, and reads:

'The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya by the owner of the patent or with his express consent'²⁶³ (own emphasis).

South Africa's experience with parallel importation has also been somewhat controversial. Until fairly recently, the country's legislation did not include this flexibility. The first, highly publicised, attempt was to include it in the 1997 amendments to the Medicines Act²⁶⁴ and resulted in a major legal challenge by the pharmaceutical industry.²⁶⁵ Opposition to the case, both within and outside the country, resulted in the eventual withdrawal of the case.²⁶⁶ To give effect to this provision, the government subsequently passed regulations,²⁶⁷ which proved to be highly onerous with the result that this flexibility has not been used. Finally, in 2002, the Patents Act was amended to facilitate international exhaustion.²⁶⁸ This provision too has not been invoked to access medicines.

Botswana utilised this flexibility when it declared HIV/AIDS a national emergency in 2000 and began importing cheaper ARV drugs.²⁶⁹

Recommendations

1. The most permissive parallel importation regime, including international exhaustion and the inclusion of legitimately commercialized products, such as

²⁵⁹ Clause 37 Industrial Property Regulations (2002).

²⁶⁰ Lettington and Munyi (2004), 20.

²⁶¹ *Pfizer Inc. v. Cosmos Limited* (Case No. 49 of 2006), Industrial Property Tribunal, at Nairobi, April 25, 2008.

²⁶² As reported in Afro-IP, *Kenya: Tribunal Finds Pfizer's Azithromycin Dihydrate Patent Infringed* (2008) <https://afro-ip.blogspot.com/2008/07/kenya-tribunal-finds-pfizers.html> (Afro-IP 2008).

²⁶³ Amended section 58.2 Kenya Industrial Property Act.

²⁶⁴ Section 15C Medicines and Related Substances Act No 101 of 1965 (South Africa Medicines Act).

²⁶⁵ *Pharmaceutical Manufacturers Association & Others v Government of RSA*, TPD Case No 4183/98 (unreported).

²⁶⁶ This issue has been widely documented in the literature. See, for example, M Heywood, *South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realize the Right to Health* (2009), J of Human Rights Practice 1, no. 1, 14-36 <https://academic.oup.com/jhrp/article/1/1/14/2188684> (Heywood 2009).

²⁶⁷ Regulation 7 Medicines Act Regulations 2003.

²⁶⁸ Section 45(2) Patents Act No 57 of 1978 (South Africa Patents Act).

²⁶⁹ See, Kamwendo, *A Critical Discussion on Botswana's Access to Medicine and TRIPS Flexibilities* (2016), Unpublished LLM Thesis,

https://researchspace.ukzn.ac.za/xmlui/bitstream/handle/10413/15016/Kamwendo_Tamanda_Agatha_2017.pdf?sequence=1&isAllowed=y; J Court and J Young, *Bridging Research and Policy on HIV/AIDS in Developing Countries: Case Study – Botswana* (2005), ODI <https://www.odi.org/sites/odi.org.uk/files/odi-assets/publications-opinion-files/4949.pdf>.

those sold under compulsory and government use licences, should be adopted.

- 2. Processes for implementing this flexibility should be streamlined and easy-to-use.**

vi) *Post-Grant Opposition*

As with pre-grant opposition, permitting third parties to challenge the validity of a patent after it has already been granted plays an important role in enforcing patentability criteria under a non-examining system.

Unlike the case of its pre-grant counterpart, provisions for post-grant opposition are fairly common—24 of the states examined in this study had some mechanism in terms of which interested parties (including the State in the DRC²⁷⁰ and Malawi²⁷¹) can challenge the validity of patents on the grounds that they failed to meet the requirements for patentability.²⁷² This ordinarily occurs through an application to the courts against the patent holder, usually for revocation of the patent, or where a patent holder files a claim for infringement against a competitor who counter-claims for revocation (see Table 3). The exception to this litigation-based approach is found in states such as Liberia,²⁷³ Malawi,²⁷⁴ Mauritius,²⁷⁵ Namibia,²⁷⁶ Uganda²⁷⁷ and Zambia²⁷⁸ where third parties may approach the office/officials responsible for administration of patents—or a tribunal dedicated to the resolution of IP disputes—to have a patent invalidated on the grounds that it fails to meet the requirements for patentability. South Africa does not have any provisions that allow third parties or the state to oppose the validity of patents after they have been granted, but it does allow interested parties to oppose the restoration of a lapsed patent,²⁷⁹ the correction of clerical errors and amendment of documents²⁸⁰ and amendments of the patent specification.²⁸¹

Recommendations

- 1. Opposition guidelines to be adopted to enable an effective administrative process, rather than a judicial process, allowing legal standing to any person, especially one acting in the public interest, and to provide for opposition on a wide range of grounds.**
- 2. Similar guidelines to be adopted for examination by the ARIPO and OAPI offices.**

²⁷⁰ Article 96 Law No. 82-001, January 1982.

²⁷¹ Section 50 Patents Act (Chapter 49:02) 1958.

²⁷² These States are Botswana, Comoros, DRC, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mauritius, Mozambique, Namibia, Rwanda, Sao Tome and Principe, the Seychelles, South Africa, South Sudan, (North) Sudan, eSwatini, Tanzania and Zambia.

²⁷³ Section 13.14(b) Liberia Intellectual Property Act, 2016.

²⁷⁴ Section 22 Patents Act (Chapter 49:02) 1958.

²⁷⁵ Section 25 Patents, Industrial Designs and Trademarks Act 2002.

²⁷⁶ Section 65 Industrial Property Act, 2012 (Act No. 1 of 2012).

²⁷⁷ Section 32 The Industrial Property Act, 2014.

²⁷⁸ Section 91 The Patents Act, 2016 (Act No. 40 of 2016).

²⁷⁹ S 47(2) Patents Act, 1978 (as amended).

²⁸⁰ S 49(5) Patents Act, 1978 (as amended).

²⁸¹ S 51(3)(a) Patents Act, 1978 (as amended).

Table 3: Patent Laws Related to Post-grant Flexibilities

State	Term	Involuntary Licences	Parallel Imports	Research Exception	'Bolar' Exception	Post-Grant Opposition
Angola	15	CL granted for non-working and in the public interest, or where there is insufficient exploitation	N/A	N/A	N/A	N/A
Botswana	20	CL granted in the public interest, including for the purposes of public health	Explicitly provides for parallel importation of generic pharmaceuticals where in the public interest to do so.	Yes	N/A	Any interested party may approach court to invalidate patent.
Burundi	20	CL granted in the public interest, including for the purposes of public health, abuse of patent, anti-competitive and non-working	Yes	Yes	Yes	N/A
Comoros	5,10, 15 or 20	CL granted for non-working and abuse of patent	N/A	N/A	N/A	Any interested party may approach court to invalidate patent.
DRC	15	CL granted if patent is not worked in an efficient, conscientious and continuous manner	N/A	Yes	N/A	Any interested party or state acting ex officio may approach court to invalidate patent.
Gambia	15	CL granted for non-working or insufficient working Government use for public interest, including health needs	N/A	N/A	N/A	Any interested party may approach court to invalidate patent.
Ghana	20	CL granted for anti-competitive practices, refusal to license, failure to exploit and dependent patents Government use for public interest, including health needs	N/A	Yes	N/A	Any interested party may approach court to invalidate patent.
Kenya	20	CL granted for non-working Government use for public interest, in particular health needs.	Yes	Yes	Yes	Any interested party may approach court to invalidate patent or have it revoked.

Lesotho	15	'Non-voluntary licence' granted for non-working or insufficient working Government use for public interest, including health needs.	N/A	Yes	N/A	Any interested party may approach court to invalidate patent.
Liberia	20	CL granted for public interest, including health	N/A	Yes	N/A	Any interested party may apply to Director General or approach court to invalidate patent.
Madagascar	15	CL granted for insufficient working, unreasonable refusal of licence or failing to meet demand in Madagascar. Government use for any reason related to public interest needs	N/A	N/A	N/A	N/A
Malawi	16	CL granted for medicines or substances capable of being used in medicines Government use, with no restrictions as to reasons	Where government use authorized, or during a state of emergency where exporting patented products regarded as government use	N/A	N/A	Any interested party, including the state, may approach the Patents Tribunal to invalidate patent.
Mauritius	20	'Non-voluntary licence' granted for non-working or insufficient working Government use for grounds, including public health needs	N/A	Yes	N/A	Any interested party may approach the Industrial Property Tribunal to invalidate patent.
Mozambique	20	CL granted for failure to exploit an invention where invention is in the public interest, which includes public health needs.	N/A	Yes	N/A	Any interested party may approach the court to declare nullity of patent rights.
Namibia	20	CL granted in the public interest, including health and in the case of a national health crisis, where relevant, pharmaceuticals require a licence for importation Government use, where a vital public interest requires exploitation of patent	Provides for parallel imports	Yes	Yes	Any interested party may approach Industrial Property Tribunal to invalidate patent.

Rwanda	20	Provides for CL on the grounds of public interests, abuse and insufficient working 'ex officio' compulsory licence may be granted on grounds of public health	Minister may declare patent rights exhausted in order to authorise importation	Yes	Yes	Any interested party may approach court to invalidate patent.
Sao Tome and Principe	20	Government use for public interest, including health needs	N/A	Yes	N/A	Any interested party may approach court to have a patent annulled.
Seychelles	20	'Non-voluntary licence' granted on the grounds of public interest , which includes health, as well as non-working	N/A	Yes	Yes	Any interested party may approach court to invalidate patent.
Sierra Leone	20	CL granted for non-working or insufficient working Government use for public interest, including health needs	N/A	Yes	N/A	N/A
South Africa	20	CL granted on the grounds of abuse, non-working, unmet demand, prejudice to trade by refusal of licence, demand met by importation, price excessive and for dependent patent	N/A	N/A	Yes	Any interested party may approach court to revoke patent.
South Sudan	20	CL granted for non-working and similar reasons	N/A	Yes	N/A	Any interested party, or Patent Authority, may approach court to have patent declared null and void.
(North) Sudan	20	CL granted for non-working, insufficient working, working prevented or hindered by the importation of the patented article, unfair prejudice to commercial activities	N/A	Yes	No	Any interested party, or Patent Authority, may approach court to have patent declared null and void.
eSwatini	20	Provides for CL in the public interest, in particular health needs CL provisions also apply to government	N/A	N/A	N/A	Any interested party may approach court to invalidate patent.

		use				
Tanzania	10	CL be granted for products declared to be of vital importance, including to public health Government use, for a vital public interest, in particular health needs	N/A	Yes	No	Any interested party may approach court to invalidate patent.
Uganda	20	CL granted for non-working, anti-competitive behaviour and use for vital public interest, including to public health needs	Yes	Yes	Yes	Any interested party may approach the registrar to reconsider the granting of the patent or approach the court to invalidate the patent.
Zambia	20	CL granted for the public interest, including health, or non-working of the patent in Zambia. Government use for grounds including public health needs	Provides for exporting of patented medicines provided not patented in receiving state, or government has authorized importing	Yes	Yes	Any interested party, including the state, may approach the registrar to have a patent revoked.
Zanzibar	20	CL granted in the public interest, including for the purposes of public health, abuse of patent, anti-competitive and non-working Government use for public interest in particular health needs	Yes	Yes	Yes	Any interested party may approach court to invalidate patent.
Zimbabwe	20	Compulsory licences may be granted for abuse or insufficient use of the invention Government use provided for with no specific requirements	Provides for parallel imports	N/A	Yes	Any interested party may approach court to invalidate patent.

FLEXIBILITIES OUTSIDE IP AND INDUSTRIAL PROPERTY LEGISLATION: COMPETITION LAW AND POLICY

In addition to the public health flexibilities, which States can adopt and incorporate into their IP law, reforms in other areas of law may also have a positive impact on access to healthcare. The use of competition law and policy has been promoted as an important tool in order to reduce the cost of treatment for several reasons. Among them are greater room to secure relatively flexible rules; the accommodation of different competition approaches may permit a wider variety of remedial actions; and the potential to empower a broad range of affected parties to request or initiate enforcement action.²⁸² The UNDP Guidebook points out that, as this area of law and policy is relatively new in the context of low- and middle-income countries (LMICs), financial and capacity resource constraints can be a major inhibiting factor. As a result, few LMICs have either the legislative framework or the enforcement capability to make effective use of this flexibility.²⁸³

South Africa may be regarded as a leader in this regard. It has a progressive and pro-development legal framework²⁸⁴ and efficient institutional structures in the Competition Commission, Competition Tribunal and Competition Appeal Court.²⁸⁵ With regard to its role in enhancing access to medicines, it can boast two significant successes. The first, in 2002, related to a complaint to the Competition Commission against two pharmaceutical companies based on excessive pricing of ARVs.²⁸⁶ The Commission found that the companies had abused their dominant positions in their respective ARV markets, and hence contravened the Competition Act. This finding was referred to the Competition Tribunal for determination, but before the matter could be heard, the companies negotiated voluntary licences, which resulted in substantial reductions in the prices of the ARVs concerned.²⁸⁷ The second case, in 2007, involved a complaint against another company on the grounds of refusal to licence.²⁸⁸ Here again, the company negotiated voluntary licences, with similar results.²⁸⁹

It has been reported that African countries are increasingly implementing and enforcing competition laws on a national and regional basis. Among the countries reputed to possess established competition authorities are Kenya and Zambia, with Malawi and Tanzania also having promulgated competition laws.²⁹⁰ The practice in these jurisdictions appears to relate primarily to mergers and investigation of cartels. No application to the direct regulation of the medicines market has been reported.

²⁸² UNDP, *Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries* (2014) <https://hivlawcommission.org/wp-content/uploads/2017/06/UNDP-Using-Competition-Law-to-Promote-Access-to-Medicine-05-14-2014-1.pdf> (UNDP 2014) p 8.

²⁸³ UNDP (2014), 36.

²⁸⁴ Competition Act 89 of 1998 (South Africa Competition Act).

²⁸⁵ Chapter 4, South Africa Competition Act.

²⁸⁶ *Hazel Tau and others v GlaxoSmithKline and Boehringer Ingelheim*, Competition Commission Case Number: 2002 Sep 226.

²⁸⁷ UNDP, *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* (2013), 91-93 https://www.undp.org/content/dam/undp/library/hiv/aids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf (UNDP 2013).

²⁸⁸ *Treatment Action Campaign v MSD (Pty) Ltd & Another* (November 2007) Competition Commission of South Africa.

²⁸⁹ UNDP (2013), 93-95.

²⁹⁰ See LexAfrica, *Developments in Competition Law in Africa* (2018), <https://www.lexafrica.com/developments-in-competition-law-in-africa/> (LexAfrica 2018).

Recommendations

- 1. Legal and institutional frameworks to be adopted to facilitate a robust competition environment, with particular regard to eliminating the abuse of dominant position in the medicines market.**
- 2. In particular, provision to be made in both patent/industrial property and competition legislation for compulsory and government use licences, including judicial licences, not requiring prior negotiations and domestic use limitations, and requiring no or minimal remuneration on such licences.**

CONCLUSION

It has long been recognised that the TRIPS flexibilities are an essential tool ‘to promote access by local producers to patented pharmaceutical ingredients and also to the know-how and the technology to produce patented pharmaceuticals’.²⁹¹ However, in order for such gains to materialise, countries must reform their patent or industrial property laws to enable their full utilisation.²⁹² Reflecting on the progress made since the Doha Declaration, many countries have made great strides in improving access to healthcare through the utilisation of TRIPS flexibilities, but their adoption and use are far from optimal. The recommendations in this paper seek to offer guidance to those countries in formulating their IP regimes in order to achieve this.

The process of the adoption and implementation of the TRIPS flexibilities in national systems is but a first step on the road to health for all. The project of access to medicines is a function of several processes, not restricted to the legal measures identified here. It is informed not only by cost and affordability but also by the availability of supplies, which could be threatened by reliance on a single or a limited number of suppliers, the exhaustion of stock following a major outbreak or epidemic, or defects arising from the manufacturing process. And finally, the goal of enabling access to medicines will be dependent on the overall resilience of health systems.

²⁹¹ EAC Regional IP Policy, 26.

²⁹² Musungu and Oh (2005), 5.

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Chemin du Champ-d'Anier 17
PO Box 228, 1211 Geneva 19
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
<http://www.southcentre.int>

ISSN 1819-6926