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

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

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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), 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 Health in November 2001, they have increasingly focused on the domestication of TRIPS flexibilities in national law and the extent of their use. 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 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.

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

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

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. Many factors contribute to the state of health in the region, including the availability of health services, health system performance and health system investments.

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.

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.’ 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.

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?

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10 Ibid.
11 Ibid.
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 metropoles 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. 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) and the Organisation Africaine de la Propriete Intellectuelle (OAPI) and Regional Economic Communities (RECs). 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 Agreement, 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. This distinction makes a significant difference to the manner in which patents granted at the regional structure are received in their respective Member countries.

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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
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 Berne and Paris Conventions were insufficient to protect their interest at the global scale and were not being enforced adequately by many developing countries.

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?’ 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.

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.

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. 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.

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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).
27 ‘t Hoen (2009), 2.
The Doha Declaration is a seminal document as it foregrounds the public health concerns 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.

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\(^{30}\) “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: ARlPO, 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, 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. The 15 LDC States can thus benefit from the LDC transition provision. Four of them are not WTO Member States at present, namely, Sao Tome and Principe, South Sudan, (North) Sudan 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. In a recent review on the patent laws of several African States, Machemedze 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. 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. The Roadmap defined its

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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.
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_sudan_e.htm.
43 Munyuki and Machemedze (2010).
solutions around three strategic pillars: diversified financing, access to medicines and enhanced governance.\textsuperscript{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.’\textsuperscript{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 Principle, Uganda and Zambia have all had promulgated new laws regulating IP since 2009 (see Table 1).

\textsuperscript{45} AU Roadmap on Shared Responsibility, 2.
\textsuperscript{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; 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. 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;
2. Enforce stricter patentability criteria;
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;
4. Strengthen provisions relating to research exceptions;
5. Provide for the early working (bolar) exception;
6. Provide for test data protection;
7. Provide for extensive disclosure in patent applications to facilitate thorough search and examination;
8. Provide for pre- and post-grant administrative opposition of patents;
9. Provide for international exhaustion in all forms of IP;
10. Provide for the grant of compulsory licences on grounds and conditions that enable access to medicines; and
11. Include in the patent laws provisions that discourage unfair and/or anti-competitive practices.

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

b) SADC Strategy

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

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47 The EAC is a regional intergovernmental organisation of six States, comprising Burundi, Kenya, Rwanda, South Sudan, Tanzania and Uganda.
Procurement of Essential Medicines and Health Commodities.\textsuperscript{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.’\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{68}

\textsuperscript{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.

\textsuperscript{62} SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities, 2013-2017

\textsuperscript{63} While this study focuses on Member States of ARIPO, the EAC and SADC, further research will be conducted on the remaining African States.

\textsuperscript{64} https://www.export.gov/article?id=Congo-Democratic-Republic-Protection-of-Property-Rights.

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 ARIPO\(^69\) is instructive. A 2014 study on the ARIPO Protocol on Patents\(^70\) 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.\(^74\)

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\(^69\) 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.


\(^71\) Shashikant (2014), 45.

\(^72\) Shashikant (2014), 46.


### Table 1: Overview of African States and Their Patent Laws

<table>
<thead>
<tr>
<th>STATE</th>
<th>LDC Status</th>
<th>Regional Org.</th>
<th>Patent Law</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angola</td>
<td>LDC</td>
<td>SADC</td>
<td>Industrial Property Law, No. 3 of 1992</td>
</tr>
<tr>
<td>Botswana</td>
<td>Non-LDC</td>
<td>ARIPo, SADC</td>
<td>Industrial Property Act, 2010 (Act No. 8 of 2010)</td>
</tr>
<tr>
<td>Burundi</td>
<td>LDC</td>
<td>EAC</td>
<td>Industrial Property Law, No. 1 of 2009</td>
</tr>
<tr>
<td>Comoros</td>
<td>LDC</td>
<td>SADC</td>
<td>Law of July 5, 1844, on Patents for Inventions</td>
</tr>
<tr>
<td>DRC</td>
<td>LDC</td>
<td>SADC</td>
<td>Law No. 82-001, January 1982</td>
</tr>
<tr>
<td>Gambia</td>
<td>LDC</td>
<td>ARIPo</td>
<td>Industrial Property Chapter 95:03 Act 12 of 1989</td>
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<td>Ghana</td>
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<td>Patents Act, 2003 (Act 657)</td>
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<td>Non-LDC</td>
<td>ARIPo, EAC</td>
<td>Industrial Property Act, (Act No. 3 of 2001 as amended up to Act No. 11 of 2017)</td>
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<td>Lesotho</td>
<td>LDC</td>
<td>ARIPo, SADC</td>
<td>Industrial Property Amendment Act, 1997</td>
</tr>
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<td>Madagascar</td>
<td>LDC</td>
<td>SADC</td>
<td>Ordinance No. 89-019 Establishing Arrangements for the Protection of Industrial Property in Madagascar (of July 31, 1989)</td>
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<td>Malawi</td>
<td>LDC</td>
<td>ARIPo, SADC</td>
<td>Patents Act (Chapter 49:02) (1958)</td>
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<td>Non-LDC</td>
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<td>Patents, Industrial Designs and Trademarks Act 2002</td>
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<td>Mozambique</td>
<td>LDC</td>
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<td>Industrial Property Code (approved by Decree No. 47/2015 of December 31, 2015)</td>
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<td>Industrial Property Act, 2012 (Act No. 1 of 2012)</td>
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<td>Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property</td>
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<td>Sao Tome and Principe</td>
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<td>Industrial Property Code Decree-Law No. 23/2016</td>
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<td>ARIPo</td>
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<tr>
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<td>SADC</td>
<td>Patents Act, 1978 (as amended)</td>
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<td>Industrial Property Law, No. 6 of 1997</td>
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<td>ARIPo, SADC, EAC</td>
<td>Patents Act, 1987</td>
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<td>ARIPo, EAC</td>
<td>The Industrial Property Act, 2014</td>
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<td>ARIPo, SADC</td>
<td>The Patents Act, 2016 (Act No. 40 of 2016)</td>
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<td>EAC</td>
<td>Industrial Property Act No. 4 of 2008</td>
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<td>Zimbabwe</td>
<td>Non-LDC</td>
<td>ARIPo, SADC</td>
<td>The Patents Act (Chapter 26:03) (amended by Act 9 of 2002)</td>
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</table>
**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

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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](https://www.who.int/phi/publications/int_prop_role_local_prod_opportunities-challenges.pdf)

76 [https://www.wto.org/english/tratop_e/minist_e/min01_e/mindecl_trips_e.htm](https://www.wto.org/english/tratop_e/minist_e/min01_e/mindecl_trips_e.htm)

77 Article 66.1 of TRIPS.

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.\textsuperscript{[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):\textsuperscript{[80]}

1. Angola (2005),
3. Burkina Faso (2005),
4. Burundi (2005),
5. Cape Verde Islands (2004),
7. Chad (2004 and 2007),
8. Comoros (2007),
10. Democratic Republic of Congo (2005),
11. Eritrea (2005),
14. Guinea Bissau (2005),
15. Lesotho (2004 and 2006),
17. Mauritania (2004),
18. Mozambique (twice in 2005),
20. Rwanda (twice in 2007),
21. Senegal (2006),
22. Sierra Leone (twice in 2009),
23. South Sudan,
24. Sudan,
25. Tanzania (2008),
27. Uganda (2006), and

In some cases, this use has occurred even though, strictly speaking, it is contrary to the existing law.\textsuperscript{[81]} Several States have, however, endeavoured to secure an enabling policy environment by including the transition provision into their patent laws (see Table 2).\textsuperscript{[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.


\textsuperscript{[80]} Medicines Law and Policy, TRIPS Flexibilities Database, \url{http://tripsflexibilities.medicineslawandpolicy.org/} (TRIPS Flexibilities Database).

\textsuperscript{[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.

\textsuperscript{[82]} These States are Burundi, Liberia, Rwanda and Zanzibar.
For countries such as Angola, whose existing IP legislation excludes pharmaceuticals,\(^8^3\) 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,\(^8^4\) 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.\(^8^5\)

An additional burden that hinders access to medicines relates to LDCs (and non-WTO States) that are signatories to the Harare Protocol,\(^8^6\) 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.\(^8^7\) 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.’\(^8^8\) Finally, such ambiguity potentially nullifies the additional flexibility provided in Article 31\(\text{bis}\) 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.\(^8^9\)

**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

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\(^8^3\) Article 4\((c)\) Industrial Property Law, No. 3 of 1992.

\(^8^4\) These States are Liberia, and Madagascar.

\(^8^5\) Thorpe (2002), 11.

\(^8^6\) These States are Ghana, Lesotho, Liberia, Malawi, Mozambique, Rwanda, Sao Tome and Principe, Sierra Leone, South Sudan, (North) Sudan, eSwatini, Tanzania, Uganda and Zambia.


\(^8^8\) See Civil Society ARIPo Proposals (2019), 14.

\(^8^9\) Article 31\((\text{bis})\) 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 31bis of the TRIPS Agreement

4. Those LDCs that are signatories to the Harare Protocol wherein patents granted by ARIFO are applicable in their countries unless they opt-out, should immediately reject all such patents, inform ARIFO 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 microorganisms, and essential biological processes for their production (other than non-biological and microbiological processes). 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. 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. 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 2005 (no new forms or new uses, among others, of a known substance unless enhanced efficacy is proven), and Argentina’s patent examination guidelines, 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. 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. 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.
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.
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.’
- Burundi: contains the additional exclusion of ‘natural substances, even if they had been purified, synthesized or isolated in another manner.’
- 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.’
- 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.’
- 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.’
- 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.’
- 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.’
- Uganda: excludes pharmaceuticals by virtue of its LDC status.
- 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
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.\textsuperscript{105}

- Zanzibar: specifically excludes 'new uses of known product or process'.\textsuperscript{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,\textsuperscript{107} Zimbabwe\textsuperscript{108} and (surprisingly for its generally more liberal use of flexibilities) Zambia.\textsuperscript{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:\textsuperscript{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).

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

\textsuperscript{106} Section 3(1)(v) Industrial Property Act No 4 of 2008.

\textsuperscript{107} Section 2 Patents Act (Chapter 49:02) (1958).


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

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

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


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

114 Kisch IP.

115 iHub Kenya, Patenting in Kenya (undated)

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. 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.’ Additionally, final administrative decisions shall be subject to review by a judicial or quasi-judicial authority. 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. The section further elaborates the process for and disposition of the application to oppose.

- **Zimbabwe**: The provisions in this legislation 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. The ensuing section further elaborates the process for and disposition of the application to oppose.

- **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
prejudicial to him.\textsuperscript{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.\textsuperscript{127} The ensuing sub-sections deal with the process and disposition of the opposition.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{132} The ensuing sub-paragraphs provide for the process and hearing of the opposition.\textsuperscript{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.\textsuperscript{134} The ensuing sub-sections deal with the procedure and, if the registrar deems necessary, the hearing of the objection.\textsuperscript{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.\textsuperscript{136} The ensuing sub-paragraphs deal with the procedure and, if the registrar deems necessary, the hearing of the objection.\textsuperscript{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.\textsuperscript{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.\textsuperscript{139} The same report (Shashikant 2014)
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.\footnote{140}

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

\footnote{140}{Shashikant (2014), 64.}
\footnote{141}{See, for example, MSF. *MSF launches online resource for challenging unwarranted drug patents* (2012) \url{https://www.msfaccess.org/msf-launches-online-resource-challenging-unwarranted-drug-patents} (MSF 2012).}
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<th>STATE</th>
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<th>Patentability Criteria</th>
<th>Patent Examination</th>
<th>Pre-Grant Opposition</th>
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</thead>
<tbody>
<tr>
<td>Angola</td>
<td>Excludes pharmaceuticals</td>
<td>Absolute novelty</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Botswana</td>
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<td>Formal</td>
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<td>Pharmaceuticals patentable</td>
<td>Absolute novelty</td>
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<td>N/A</td>
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<td>Kenya</td>
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<td>Substantive</td>
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<tr>
<td>Country</td>
<td>Patents Status</td>
<td>Rules on Novelty</td>
<td>Examination Type</td>
<td>Notes</td>
</tr>
<tr>
<td>--------------------------</td>
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<td>-------</td>
</tr>
<tr>
<td>Namibia</td>
<td>Pharmaceutical patentable</td>
<td>Absolute novelty</td>
<td>Substantive</td>
<td>N/A</td>
</tr>
<tr>
<td>Rwanda</td>
<td>Exclusion of pharmaceutical products, for the purposes of international conventions to which Rwanda is party</td>
<td>Absolute novelty</td>
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<td>Pharmaceuticals patentable</td>
<td>Absolute novelty</td>
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<tr>
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<td>Pharmaceuticals patentable</td>
<td>Absolute novelty</td>
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<td>South Africa</td>
<td>Pharmaceuticals patentable</td>
<td>Complies with Article 27.1</td>
<td>Formal</td>
<td>N/A</td>
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<tr>
<td>South Sudan</td>
<td>Pharmaceuticals patentable</td>
<td>Complies with Article 27.1</td>
<td>Formal</td>
<td>N/A</td>
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<td>(North) Sudan</td>
<td>Pharmaceuticals patentable</td>
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<tr>
<td>eSwatini</td>
<td>Pharmaceuticals patentable</td>
<td>Complies with Article 27.1</td>
<td>Substantive</td>
<td>N/A</td>
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<tr>
<td>Tanzania</td>
<td>Pharmaceuticals patentable</td>
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<td>Complies with Article 27.1</td>
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Note: N/A stands for Not Applicable.
<table>
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<th>Country</th>
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<th>novelty</th>
<th>Examination</th>
<th>Opposition</th>
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<td>Relative novelty</td>
<td>Substantive examination</td>
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<tr>
<td>Zanzibar</td>
<td>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</td>
<td>Absolute novelty</td>
<td>Substantive examination</td>
<td>Any interested party may oppose grant</td>
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<tr>
<td>Zimbabwe</td>
<td>Pharmaceuticals patentable</td>
<td>Complies with Article 27.1</td>
<td>Formal</td>
<td>Any interested party, including the state, may oppose grant</td>
</tr>
</tbody>
</table>
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, Comoros, Liberia, Mozambique, Rwanda, Sierra Leone, Uganda, and Zambia. The non-WTO States are Sao Tome and Principe, North and South Sudan, and Zanzibar.

Seven LDCs provide protection for less than 20 years. Those providing a minimum of 15 years are Angola, the DRC (for drugs only), Gambia, Lesotho and Madagascar. Malawi provides for 16 years and Tanzania 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

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142 Article 62 Law No 1/13 of July 28, 2009
143 Article 36 Loi du 5 juillet 1844 sur les brevets d’invention
145 Article 73 Industrial Property Code (approved by Decree No. 47/2015 of December 31, 2015)
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).
152 Section 13(1)(a) Zanzibar Industrial Property Act, 2008 (Act No. 4 of 2008).
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 Principe,165 Seychelles,166 South Africa,167 Uganda,168 Zambia,169 Zanzibar,170 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

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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.
163 Section 43(20) Industrial Property Act No 1 of 2012.
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.
170 Section 11(4)(v) Industrial Property Act No. 4 of 2008.
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 31bis. 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


the necessity to protect public health: Botswana,179 Burundi,180 Liberia,181 Mozambique,182 Mauritius,183 Namibia,184 the Seychelles,185 eSwatini,186 Tanzania,187 Zambia188 and Zanzibar.189 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.
182 Article 92.2 Industrial Property Code (approved by Decree No. 47/2015 of December 31, 2015).
184 Section 57 Industrial Property Act, 2012 (Act No. 1 of 2012).
185 Section 23 Industrial Property Act 2014 (Act No. 7 of 2014).
189 Section 14.1(a) Industrial Property Act No. 4 of 2008.
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).
197 Section 66(1)(a) The Industrial Property Act, 2014. Uganda has also adopted the TRIPS Article 31bis 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).
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,\(^{204}\) Zambia\(^{205}\) 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 for—a provision designed to secure, in this instance, access to medicines to the public.\(^{208}\) Similar provisions are found in the legislation of Zimbabwe\(^{209}\) 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).
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.**

\(^{201}\) 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.
\(^{212}\) 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.

d) 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, Burundi, the DRC, Ghana, Kenya, Lesotho, Liberia, Mauritius, Mozambique, Namibia, Rwanda, Sao Tome and Principe, the Seychelles, Sierra Leone, South Sudan, (North) Sudan, Tanzania, Uganda, Zambia, and Zanzibar.

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 pharmacists 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.

d) Parallel Imports

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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.
222 Article 75(a) Industrial Property Code (approved by Decree No. 47/2015 of December 31, 2015).
225 Section 60(1)(a) Industrial Property Act 2014 (Act No. 7 of 2014).
228 Section 23(1) Patent Law No. 58 of 1971.
231 Section 75(1)(a) The Patents Act, 2016 (Act No. 40 of 2016).
232 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. 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, Burundi, Ghana, Kenya, Liberia, Namibia, Seychelles, South Africa, Sierra Leone, Zambia, Zanzibar and Zimbabwe. Madagascar, Mozambique, Rwanda, Sao Tome and Principe, South Sudan, eSwatini and Uganda 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 emergency or granting a government use or compulsory 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. 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.’

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:

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

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.

The continued use of this flexibility, however, may be in jeopardy as a result of the 2008 decision in Pfizer Inc. v. Cosmos Limited, 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.’

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’ (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 Act and resulted in a major legal challenge by the pharmaceutical industry. Opposition to the case, both within and outside the country, resulted in the eventual withdrawal of the case. To give effect to this provision, the government subsequently passed regulations 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. 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.

**Recommendations**

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

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259 Clause 37 Industrial Property Regulations (2002).
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).
268 Section 45(2) Patents Act No 57 of 1978 (South Africa Patents Act).
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 DRC\(^{270}\) and Malawi\(^{271}\)) 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,\(^ {276}\) Uganda\(^ {277}\) and Zambia\(^ {278}\) 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 documents\(^ {280}\) 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.

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\(^{270}\) 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.
\(^{274}\) Section 22 Patents Act (Chapter 49:02) 1958.
\(^{276}\) 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

<table>
<thead>
<tr>
<th>State</th>
<th>Term</th>
<th>Involuntary Licences</th>
<th>Parallel Imports</th>
<th>Research Exception</th>
<th>‘Bolar’ Exception</th>
<th>Post-Grant Opposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angola</td>
<td>15</td>
<td>CL granted for non-working and in the public interest, or where there is insufficient exploitation</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
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<td>20</td>
<td>CL granted in the public interest, including for the purposes of public health</td>
<td>Explicitly provides for parallel importation of generic pharmaceuticals where in the public interest to do so.</td>
<td>Yes</td>
<td>N/A</td>
<td>Any interested party may approach court to invalidate patent.</td>
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<td>Burundi</td>
<td>20</td>
<td>CL granted in the public interest, including for the purposes of public health, abuse of patent, anti-competitive and non-working</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Comoros</td>
<td>5, 10, 15 or 20</td>
<td>CL granted for non-working and abuse of patent</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Any interested party may approach court to invalidate patent.</td>
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<td>DRC</td>
<td>15</td>
<td>CL granted if patent is not worked in an efficient, conscientious and continuous manner</td>
<td>N/A</td>
<td>Yes</td>
<td>N/A</td>
<td>Any interested party or state acting ex officio may approach court to invalidate patent.</td>
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<td>Gambia</td>
<td>15</td>
<td>CL granted for non-working or insufficient working</td>
<td>N/A</td>
<td>N/A</td>
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<td>Any interested party may approach court to invalidate patent.</td>
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<td>Government use for public interest, including health needs</td>
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<td>Ghana</td>
<td>20</td>
<td>CL granted for anti-competitive practices, refusal to license, failure to exploit and dependent patents</td>
<td>N/A</td>
<td>Yes</td>
<td>N/A</td>
<td>Any interested party may approach court to invalidate patent.</td>
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<td>Kenya</td>
<td>20</td>
<td>CL granted for non-working</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Any interested party may approach court to invalidate patent or have it revoked.</td>
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<td>Country</td>
<td>Quota</td>
<td>Overview</td>
<td>N/A</td>
<td>Yes</td>
<td>N/A</td>
<td>Any interested party may approach court to invalidate patent.</td>
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<td>Lesotho</td>
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<td>'Non-voluntary licence' granted for non-working or insufficient working</td>
<td>N/A</td>
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<td></td>
<td>Government use for public interest, including health needs.</td>
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<td>Liberia</td>
<td>20</td>
<td>CL granted for public interest, including health</td>
<td>N/A</td>
<td>Yes</td>
<td>N/A</td>
<td>Any interested party may apply to Director General or approach court to invalidate patent.</td>
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<td>Madagascar</td>
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<td>CL granted for insufficient working, unreasonable refusal of licence or failing to meet demand in Madagascar.</td>
<td>N/A</td>
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<td></td>
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<td>Government use for any reason related to public interest needs.</td>
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<td>16</td>
<td>CL granted for medicines or substances capable of being used in medicines</td>
<td>N/A</td>
<td></td>
<td>N/A</td>
<td>Any interested party, including the state, may approach the Patents Tribunal to invalidate patent.</td>
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<td></td>
<td></td>
<td>Government use, with no restrictions as to reasons.</td>
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<td>Mauritius</td>
<td>20</td>
<td>'Non-voluntary licence' granted for non-working or insufficient working</td>
<td>N/A</td>
<td>Yes</td>
<td>N/A</td>
<td>Any interested party may approach the Industrial Property Tribunal to invalidate patent.</td>
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<td>Government use for grounds, including public health needs.</td>
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<td>Mozambique</td>
<td>20</td>
<td>CL granted for failure to exploit an invention where invention is in the public interest, which includes public health needs.</td>
<td>N/A</td>
<td>Yes</td>
<td>N/A</td>
<td>Any interested party may approach the court to declare nullity of patent rights.</td>
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<td>Namibia</td>
<td>20</td>
<td>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</td>
<td>N/A</td>
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<td>Yes</td>
<td>Any interested party may approach Industrial Property Tribunal to invalidate patent.</td>
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<td>Government use, where a vital public interest requires exploitation of patent</td>
<td></td>
<td></td>
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<td>Country</td>
<td>Year</td>
<td>Description of Compulsory Licence</td>
<td>Conditions for Granting</td>
<td>Minister to Declare Patent Rights Exhausted</td>
<td>Any Interested Party Approaches Court</td>
<td>Patent Revoked by...</td>
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<td>Rwanda</td>
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<td>Provides for CL on the grounds of public interests, abuse and insufficient working</td>
<td>‘ex officio’ compulsory licence may be granted on grounds of public health</td>
<td>Yes</td>
<td>Yes</td>
<td>Any interested party may approach court to invalidate patent.</td>
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<td>Sao Tome and Principe</td>
<td>20</td>
<td>Government use for public interest, including health needs</td>
<td>N/A</td>
<td>Yes</td>
<td>N/A</td>
<td>Any interested party may approach court to have a patent annulled.</td>
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<td>Seychelles</td>
<td>20</td>
<td>‘Non-voluntary licence’ granted on the grounds of public interest, which includes health, as well as non-working</td>
<td>N/A</td>
<td>Yes</td>
<td>Yes</td>
<td>Any interested party may approach court to invalidate patent.</td>
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<td>20</td>
<td>CL granted for non-working or insufficient working</td>
<td>Government use for public interest, including health needs</td>
<td>N/A</td>
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<td>South Africa</td>
<td>20</td>
<td>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</td>
<td>N/A</td>
<td>N/A</td>
<td>Yes</td>
<td>Any interested party may approach court to revoke patent.</td>
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<td>South Sudan</td>
<td>20</td>
<td>CL granted for non-working and similar reasons</td>
<td>N/A</td>
<td>Yes</td>
<td>N/A</td>
<td>Any interested party, or Patent Authority, may approach court to have patent declared null and void.</td>
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<td>(North) Sudan</td>
<td>20</td>
<td>CL granted for non-working, insufficient working, working prevented or hindered by the importation of the patented article, unfair prejudice to commercial activities</td>
<td>N/A</td>
<td>Yes</td>
<td>No</td>
<td>Any interested party, or Patent Authority, may approach court to have patent declared null and void.</td>
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<td>eSwatini</td>
<td>20</td>
<td>Provides for CL in the public interest, in particular health needs</td>
<td>CL provisions also apply to government</td>
<td>N/A</td>
<td>N/A</td>
<td>Any interested party may approach court to invalidate patent.</td>
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<td>Revocation</td>
<td>Party/Approach</td>
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| 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 grant 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 framework\(^ {284}\) 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.


\(^{283}\) 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.


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

\(^{289}\) UNDP (2013), 93-95.

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’.

However, in order for such gains to materialise, countries must reform their patent or industrial property laws to enable their full utilisation.

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.

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291 EAC Regional IP Policy, 26.
292 Musungu and Oh (2005), 5.
<table>
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<tr>
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<td>1</td>
<td>November 2005</td>
<td>Overview of the Sanitary and Phytosanitary Measures in QUAD Countries on Tropical Fruits and Vegetables Imported from Developing Countries</td>
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Germán Velásquez