



BREAKING IP BARRIERS

Creating Pathways to Medicine Access

SADC Member States Snapshot Report 2012-2018

ARASA AND SAPAM REGIONAL REPORT on
SADC Member States Progress on Intellectual Property (IP) / Patent legislative frameworks
22 May 2019

Premier Hotel, Johannesburg, South Africa

Progress Report 2012-2018

Breaking IP Barriers - Creating Pathways to Medicine Access

Member States (MS) of the Southern African Development Community (SADC) have recognised the importance of Intellectual Property (IP) as an important policy instrument to drive innovation, industrial development, knowledge transfer and regional integration. Harnessing of the flexibilities contained in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS-Agreement). This will go a long way in the protection and promotion of Intellectual Property Rights (IPRs), while safeguarding public health, promoting local infrastructure and manufacturing capability; as well as food security and the protection of indigenous knowledge systems in the SADC.

As documented in this report, 2012 saw greater momentum within MS leveraging the TRIPS-flexibilities as a strategy to promote access to affordable, safe and efficacious medicines. Between 2012 and 2014, the Southern African Program on Access to Medicines and Diagnostics (SAPAM), a programme designed by the SADC Secretariat, provided technical support to Botswana, Zimbabwe, Malawi, Zambia, Lesotho, Seychelles and Eswatini to incorporate the TRIPS flexibilities into their domestic legislations. Since then, efforts have been led by SAPAM in collaboration with the AIDS and Rights Alliance for Southern Africa (ARASA) to support countries to review and revise their IP/ Patent laws and policies. Upon reviewing the progress to date in all of SADC the countries who requested technical assistance from SAPAM, only Lesotho has yet to update its IP/ Patent law.

This report chronicles progress that has been made by some of the SADC member states in the review/ revising and development of progressive IP/ Patent laws and national policies. It records progress made during the period 2012 – 2018, to advance enabling IP/Patent legislative and regulatory environments, for the improvement of access to essential pharmaceutical medicines and diagnostics. This Snapshot report documents progress recorded since the publication of the 2012 SAPAM & SADC Secretariat TRIPS-Flexibilities Inception Report (SADC 2012 Report).

Regional Progress Timeline

2012 - Baseline report established

SADC countries have incorporated TRIPS flexibilities Actual use of the legal provisions within flexibilities.

2013–14 - Seven countries assisted in reviewing their IP Legislation

Botswana, Lesotho, Malawi, Seychelles, Swaziland, Zambia, Zimbabwe

2017 - Updated regional report (2012-17)

On status of Member States incorporating TRIPS-Flexibilities Including bottlenecks and avenues to improve their national efforts

2017-18 - Focus-country Snapshots

for 16 SADC Member States on status of TRIPS flexibilities Development of an Africa-wide IP database, for consolidated views of country laws, IP policies, and identification of regional bodies (ARIPO and OAPI members)

2018 - 5 countries in SADC currently have draft Patent/ IP Bills

Madagascar, Zambia, Mauritius, Namibia and Malawi

Executive Summary

Significant strides have been made in the adoption of new and/ or in the revision of national Intellectual Property (IP)/Patent legislative frameworks. This includes the adoption of implementing regulations and national IP policies in some of the SADC countries. Least Developed Countries (LDCs) are exempted from applying some general provisions of the TRIPS until 2021 and medicines related provisions until 2033.

2018 was a significant year for the SADC Intellectual Property and Industrialisation agenda. This year saw the Republics of Zimbabwe and South Africa approve their national IP policies. These developments were further amplified by current debates in the Parliament of the Republic of Malawi on their national IP Policy. Further progress has been seen in the Republic of Namibia, where the 2012 Industrial Property Act and implementing regulations were approved by Cabinet. Namibia also tabled their draft national IP Policy for deliberation and adoption by their Parliament. Another welcomed development within the region has been the Kingdom of Eswatini tabling the Patent Bill No. 19 of 2018.

There is renewed political will within the SADC region by member states to move forward the implementation of the 2015 – 2019 SADC Pharmaceutical Business Plan (SADC Pharmaceutical Programme, Pharmaceutical Business Plan 2015-2019). The purpose of this Business plan remains to enhance the capacities of member states to effectively prevent and treat diseases that are of major concern to their national public health.

The PBP also aims at addressing pharmaceutical trade matters, in the hopes of facilitating availability and access to quality medicines and diagnostics among SADC MS. It calls on countries to strengthen their domestic IP/ Patent legislations. This is seen as a key strategy for ultimately stimulating SADC's innovation agenda. To achieve this goal, the preparedness of domestic IP/Patent legislative frameworks is prioritised, as a critical path to driving the feasibility of local manufacturing. It is envisaged that these efforts will result in the activation of a research and development into products, and processes that will safeguard SADC countries' public health obligations.

The developments documented in this report, continue to contribute towards a solid foundation for an enabling environment for the region's industrialisation agenda, as regulated and supported by the PBP in its various updates.

PROGRESS REPORT: INTELLECTUAL PROPERTY (IP) LEGISLATIVE UPDATES

Section 7 of the SADC Pharmaceutical Business Plan, provides for the Facilitating trade in pharmaceuticals within SADC.

- i) Complete the regional assessment of intellectual property and medicines legislation in MS to determine their TRIPS compliance and adaptability;
- ii) Utilise the legal expertise identified to facilitate the harmonisation of national legislation with TRIPS to incorporate TRIPS flexibilities into national legislation;
- iii) Collaborate with development partners to enable countries to protect, in clude and take advantage of the flexibilities that exist in the TRIPS Agreement as well as to assist countries in bilateral trade negotiations to conclude agreements that are not detrimental to public health;
- iv) Strengthen the capacity of Intellectual Property (IP) officers, procurement agencies and Medicines Regulatory agencies on issues of intellectual property and public health;
- v) Utilise paragraph 6 system (DOHA Declaration) or article 31bis of the TRIPS

Intellectual Property Acts enacted between 2012 – 2018 by SADC Member States

As of 2012, at least four SADC countries have enacted new IP/Patent legislations, incorporating the TRIPS flexibilities. These include: the Republics of Botswana, Mozambique, Seychelles and Namibia. Eswatini and Zambia currently have pending regulations for their IP Acts to be enforced. This while, Madagascar and Mauritius developed draft IP bills, which have been in for the last two years.

Incremental changes in the legislative environments of SADC Member States

The **Republic of Botswana** enacted their Industrial Property Act (Act No. 8 of 2010) in 2012.

The **Union of the Comoros**, the newest political member of the SADC, is regulated under the Organisation Africaine de la Propriété Intellectuelle (OAPI). Therefore all IP-related matters in the countries are regulated under this regional intellectual property agreement, which supersedes national IP law.

The **Republic of Mozambique** enacted the Industrial Property Code (Decree No. 47/2015) on 31 March 2016.

The **Republic of Namibia** promulgated the Industrial Property Act of 2012 on 1 August 2018 following the finalisation of the implementing regulations. This new Act repeals the Patents, Designs, Trade Marks and Copyright Act No. 9 of 1916 and Trade Marks in South West Africa (Act No. 48 of 1973).

The **Republic of the Seychelles** enacted the Industrial Property Act (Act No. 7 of 2014) in March 2015. This small country also acceded to WTO and the TRIPS agreement within the same period. This IP Act contains all the relevant TRIPS flexibilities.

The **Republic of Madagascar** has a reformed Intellectual Property Bill No. 043/2017 which was announced on 27 October 2017. The Bill is still under review.

The **Republic of Mauritius** Draft Industrial Property Bill was sent out for commentary early 2017.

Progress towards creating enabling environment: Implementing Rules/Regulations

One of the impeding factors in the effective implementation of legislation, is often the lack of policy regulations, which administer the provisions of the law and interpret how the law is to be practically applied. For some of the member states, it often takes years to for the implementing regulations to be adopted, after the Bills have been promulgated into law. These regulations have impeded or delayed the adoption of new IP/ Patent laws.

Case studies of delayed implementation regulations in member states:

The **Republic of Namibia** took six years to develop and consolidate the implementing regulations to the Industrial Property Bill of 2012.

The **Republic of Zambia** enacted her Patent Act in 2016; the implementation of said legislation has been stalled due to a lack of implementing regulations. Therefore; the country continues to rely on the Patents Act of 1958 (Chapter 400, as amended up to Act No. 13 of 1994). At the time of drafting, to Patents and Companies Registration Agency (PACRA) confirmed that the drafting of the regulations was at an advanced stage.

The **Kingdom of Eswatini's** Patent Act No 19 of 2018, is not yet in force due to the outstanding regulations. The patent regime in the Kingdom continues to be governed by the Patents, Design and trade Marks Act of 1936.

Consolidation of IP regimes through national Intellectual Property Policies: Progress between 2012 – 2018

A national Intellectual Property (IP) Policy can serve as a cornerstone of a country's intellectual property regime. These policies provide a holistic overview of the country's strategic objectives in leveraging IP as a tool for its various spheres of development. Member states often have to find a balance between the formulation of IP policies to support their national developmental goals. This is to strike an accord between strengthened trade positions and safeguarding of domestic Intellectual Property Rights (IPRs) and priorities. Numerous member states have commenced a process of either developing a national IP policy or have tabled same in parliament. A few have even adopted such policies.

The **Kingdom of Lesotho** has been revising her intellectual property policy since 2013. At the time of drafting, no further information was available on developments toward completing the national IP policy.

The **Republic of Malawi** has submitted the final draft of the National IP Policy for cabinet approval in October 2018.

The **Republic of Mauritius** launched the National Intellectual Property Development Plan in 2017. The plan calls for the incorporation and implementation of TRIPS flexibilities into the country's new Industrial Property Bill.

The **Republic of Mozambique** adopted the Intellectual Property Strategy 2008–2018. Similar to an IP policy, the strategy mainly addresses issues of innovation, industrial development and scientific advancement, but does not touch on the use of TRIPS flexibilities.

The **Republic Namibia** developed the draft IP Policy and Strategy, which was approved by Cabinet in June 2018. The country's draft national IP Policy has been tabled to Parliament for deliberation and adoption.

The **Republic of the Seychelles** does not have an intellectual property policy. The country relies on the National Health Policy of 2015, which promotes the use of TRIPS flexibilities and still in draft, the 'Seychelles Strategy for the Prevention and Control of Non-Communicable Diseases, 2016-2025'.

The cabinet of the **Republic of South Africa's** approved the Intellectual Property Policy Phase I in May 2018. The policy focus on moving the nation towards a knowledge economy of innovation, local manufacturing and improved productivity at the same time emphasises the importance of access to affordable health care.

The national Intellectual Property (IP) Policy 2010-2014 of the **Republic of Zambia** remains the country's latest national IP policy. Nothing further has since been published.

The National Intellectual Property Policy and Implementation Strategy of the **Republic of Zimbabwe** was adopted and published in 2018. The Policy promotes among other things, access to medicines, at affordable prices and through the exploitation of the TRIPs flexibilities. Moreover, it advocates for the use of research and development of pharmaceuticals.

It is envisioned that progress made thus far, will enable SADC countries to harness the flexibilities afforded by the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS-Agreement) and the Doha Declaration on the TRIPs Agreement and Public Health (2001), to respond to their various communicable and non-communicable disease (NCD) public health concerns.