

Developing an intellectual property rights framework in the Southern African Development Community



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Abbreviations and Acronyms

ARIPO	African Regional Intellectual Property Organization
ASEAN	Association of Southeast Asian Nations
Brics	Brazil-Russia-India-China-South Africa
COMESA	Common Market for Eastern and Southern Africa
DTI	Department of Trade and Industry, South Africa
DST	Department of Science and Technology, South Africa
EAC	East African Community
ECA	Economic Commission for Africa
ECCAS	Economic Community of Central African States
FDI	Foreign Direct Investment
IKS	Indigenous Knowledge Systems
IP	Intellectual Property
IOC	Indian Ocean Commission
NEPAD	New Partnership for Africa's Development
NIPMO	National Intellectual Property Management Office, South Africa
SACU	Southern African Customs Union
SADC	Southern African Development Community
SRO-SA	ECA Subregional Office for Southern Africa
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WIPO	World Intellectual Property Organization
UN	United Nations

Acknowledgements

Intellectual property (IP) has become one of the most important tools of global economic competition as it safeguards innovation and creativity and oils the wheel of production and service provision as knowledge and technological assets are well protected. Hence, IP has assumed an issue of global economic importance. The establishment of the World Intellectual Property Organization (WIPO) gives credence to this. For the SADC region to position itself appropriately in the intellectual property rights sphere, a framework on intellectual property is therefore imperative. This study seeks to assist in that process. Both ECA, Southern Africa Office and the SADC Secretariat would like to thank the Consultant, Ms. Caroline B. Ncube of the University of Cape Town, Department of Commercial Law, who prepared the study. The study was conducted under the overall guidance and leadership of Said Adejumobi, the Director of the Economic Commission for Africa, Sub-Regional Office for Southern Africa (ECA-SRO-SA). Oliver Maponga of ECA-SRO-SA supervised the study and finalized the publication with the guidance of Sizo Mhlana, Chief of the Subregional Data Centre of ECA-SRO-SA. The study was undertaken in collaboration with the Southern African Development Community (SADC) Secretariat through Jabulani Mthethwa, Senior Programme Officer (Trade) and Boitumelo Gofhamodimo, Director, Directorate of Trade, Industry, Finance and Investment. The finalization of the publication benefited immensely from the outcomes of a review and validation meeting organized by the SADC Secretariat in Johannesburg, South Africa, from 20- to 22 March 2017.

Executive summary

The present report presents the outcomes of a desk study on developing a framework for intellectual property rights in the Southern African Development Community (SADC). In addition to recommendations on streamlining and harmonizing issues over intellectual property rights at the national and regional levels, the report includes proposals for templates for national policy frameworks on intellectual property for adaptation by SADC member States, national legal and regulatory frameworks and national infrastructure on intellectual property rights and a road map for the adoption and adaptation of each of the proposed templates.

The key recommendations of the study for member States are clustered in the following broad areas:

- a) Policy benchmarking with regional and international norms;
- b) Policy harmonization;
- c) National intellectual property infrastructure and framework development;
- d) Use of patent flexibilities;
- e) Sharing experience in intellectual property rights;
- f) Membership of regional and international intellectual property institutions and organizations.

Specifically, the report contains recommendations for SADC member States to:

- a) Benchmark their legislation against the international legal Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)¹ and take advantage of the compliance extension granted to them under the Agreement;
- b) SADC member States classed as “developing countries” should ensure that their legislation is compliant with the Agreement;
- c) States that are not yet members of the African Regional Intellectual Property Organization should consider joining so that they may benefit from a framework that is more suited to regional socioeconomic conditions than other available international frameworks, including TRIPS, and is also compliant with TRIPS;

¹ World Trade Organization. Agreement on Trade-Related Aspects of Intellectual Property Rights. including Trade in Counterfeit Goods, Marrakech Agreement Establishing the World Trade Organization, Annex 1C, 33 ILM 1125, 1197. Available from www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm.

- d) Review the South African intellectual property framework for possible adaptation to their own circumstances;
- e) Coordinate the activities of agencies and ministries involved in intellectual property issues by developing appropriate structures such as interministerial committees or an intellectual property council in each State;
- f) Consider joining the Patent Cooperation Treaty, the international patent system of the World Intellectual Property Organization (WIPO), if they have not yet joined, so as to benefit from shared resources and efficiencies;
- g) Align regional harmonization efforts to the tripartite intellectual property agenda of the Common Market for Eastern and Southern Africa (COMESA), the East African Community and SADC, with the ultimate goal of establishing a continental free trade area and an African Economic Community;
- h) Create regional guidelines on national intellectual property policies which are aligned to the annex on intellectual property rights to the agreement on a Tripartite Free Trade Area (COMESA-EAC-SADC), to be used to review existing national intellectual property policies and to inform the formulation of policies for countries that do not have such policies;
- i) Continue to make use of the WIPO national policy toolkit and technical assistance in national policy formulation.

In addition, SADC member States should make full use of available patent-related flexibilities and:

- a) Legislate an international exhaustion regime;
- b) Issue compulsory licences under their current legislative frameworks. It is necessary to stimulate local or regional generic manufacturing capacity so that the means to implement the licences are available;
- c) Domesticate the waiver decision so that they can re-export generics and benefit from pooled procurement;
- d) Enact specific research exemption and early working (Bolar) provisions, where they have not done so already.

Furthermore, to ensure the achievement of the region-wide recommendations, the region should formulate and adopt a protocol and policy on TRIPS flexibilities, together with guidelines for the domestication of the flexibilities for member States.

Chapter 1: Introduction

A. Background

One of the priorities of the Southern African Development Community (SADC) as a regional body is to harmonize the “political and socioeconomic policies and plans” of its member States² and to seek deeper regional integration that will culminate in the establishment of a customs union (Southern African Development Community, 2003; Nkomo, 2014). Integration is an imperative of the SADC Treaty.³ The SADC regional indicative strategic development plan also makes it clear that alignment with other subregional initiatives is important.⁴ The role of SADC in deepening integration by strengthening the national and regional legal and institutional frameworks to cater for intellectual property in a harmonized manner is the most significant part of these agreements for the present report. It is clear that intellectual property is an important aspect of trade and that it is disadvantageous to exclude its detailed treatment from binding SADC instruments (Nkomo, 2014, p. 324). This is because, when trade in goods and services occurs across the borders of SADC member States, the trade partners involved will have to seek intellectual property protection in the various countries concerned. This task is very onerous, especially in cases in which the intellectual property laws of those countries are different and at times divergent and at various stages of development. In addition, the Governments of SADC member States have to negotiate differing patent laws when they seek to meet their own public interest imperatives, as when they are procuring medication for national use.

In order to minimize differences in policy and legal frameworks at the regional and continental levels, the African Regional Intellectual Property Organization harmonizes the intellectual property laws of its member States. Given that many SADC member States are also members of the African Regional Intellectual Property Organization,⁵ they can benefit from initiatives under it in as far as harmonization and other technical support is concerned. The other African intellectual property organization, the Organisation africaine de la propriété intellectuelle, also seeks to harmonize the intellectual property laws of its member States. Notwithstanding the intellectual property harmonization efforts of both the African Regional Intellectual Property Organization and its francophone counterpart, there is still an important role for the SADC secretariat to play in accelerating and deepening the harmonization of intellectual property laws among member States. Harmonization across SADC would firmly situate intellectual property in the broader context of regional trade and would be more inclusive than the harmonization provided by the African Regional Intellectual

2 The SADC member States are Angola, Botswana, the Democratic Republic of the Congo, Eswatini, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, the United Republic of Tanzania, Zambia and Zimbabwe.

3 Article 24 of the Treaty.

4 Section 6.6.3 of the Plan provides that: “There is a number of other national, subregional, continental and global initiatives that interface and have potential synergies with the interventions outlined in chapter 4. In this regard, promoting alignment and cooperation between [the Plan] and these initiatives is essential to maximize synergies and complementarities.”

5 The African Regional Intellectual Property Organization has 19 member States: Botswana, Eswatini, the Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, Sao Tome and Principe, Sierra Leone, Somalia, the Sudan, the United Republic of Tanzania, Uganda, Zambia and Zimbabwe.

Property Organization because not all SADC member States are African Regional Intellectual Property Organization members (Nkomo, 2014, p. 333). A regional approach to policy harmonization in intellectual property is thus an imperative as part of efforts towards economic integration. The current study provides an outline of what needs to be done.

In addition to the pursuit of integration, the basis of SADC harmonization efforts around intellectual property is article 24 of the SADC Protocol on Trade,⁶ in which the obligation for those States who are members of both SADC and the World Trade Organization (WTO) to comply with TRIPS, including its provisions on trade in counterfeit goods, is reiterated. All SADC member States are also members of WTO, and so they are bound by TRIPS. Seychelles was the last SADC member State to join WTO, becoming a member on 26 April 2015.⁷

The SADC secretariat has a primary role in assisting member States with TRIPS implementation by helping them to overcome the challenges identified in a 2012 audit report (United States of America, 2012) and confirmed by a 2013 study (United Nations, 2015). In particular, it was noted in the audit report that: “As in other areas of SADC’s regional agenda, in IP rights there is a large discrepancy in member State legal frameworks, levels of development for such protection as well as in protection coverage, enforcement issues, etc.” (United States of America, 2012). The 2013 study contained the same observation and highlighted the fact that intellectual property rights systems in the SADC region were, in general, poor, with the exception of South Africa. That was due to many factors, including outdated legislation and the general lack of intellectual property rights frameworks in some member States. It was noted in the study that “most member States are not TRIPS-compliant. Furthermore, only two SADC member States (Zimbabwe and Botswana) have domesticated the ARIPO framework.” (United Nations, 2015, p. 61).

It is important to note that the last two of the three identified shortcomings cannot justly be ascribed to all SADC member States. First, the failure to domesticate the African Regional Intellectual Property Organization framework can be ascribed only to its member States. As noted earlier, of the current SADC member States, Angola, the Democratic Republic of the Congo, Madagascar, Mauritius, Seychelles and South Africa are not members of the African Regional Intellectual Property Organization. These States may be encouraged to consider joining it and thereafter to domesticate its intellectual property framework in order to strengthen the domestic environment. Second, not all member States are as yet required to be TRIPS-compliant because some of them are least developed countries, and accordingly they are covered by the prevailing compliance transition period. It is important to emphasize that this state of affairs will continue as a result of the further extension of the TRIPS compliance transition period for least developed countries to 1 July 2021, or sooner if a country

⁶ Article 24 of the SADC Protocol on Trade (www.sadc.int/files/4613/5292/8370/Protocol_on_Trade1996.pdf) provides that member States shall “adopt policies and implement measures within the Community for the protection of intellectual property rights, in accordance with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)”.

⁷ World Trade Organization member information on Seychelles is available from www.wto.org/english/thewto_e/countries_e/seychelles_e.htm (accessed 13 November 2017).

graduates to developing country status before that date.⁸ In addition, the 2012 audit report further highlights that “the SADC region (with the notable exception of South Africa) is not a significant source of economic activity requiring protection of patents, copyrights, [trademarks], geographic indicators etc. Hence, the economic rationale for full implementation of the agreement is limited” (United States of America, 2012, p. 98).

This observation appears to suggest static development processes with regard to intellectual property in the SADC region. As economies develop, however, such systems become imperative as part of an industrial development strategy.

These arguments are supported by academic literature, which states that TRIPS was a compromise between the interests of developed and developing countries and adds that the Agreement has turned out to the detriment of developing countries in some respects (Ncube (2016a), p. 14; Deere (2008), p. 1; Ghidini (2014)). During the TRIPS negotiations, developing countries expressed concern that the agreement would hinder the achievement of their developmental goals and would be unlikely to yield significant benefits for them.

Given this, SADC member States that are classed as least developed countries, namely, Angola, the Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mozambique, the United Republic of Tanzania and Zambia, should not hasten to adopt TRIPS standards prematurely and before the expiry of the compliance transition period. Instead, they should put national legal and physical infrastructure in place before adopting TRIPS. Experts have criticized (Deere, 2008, p. 240) the strategy pursued by member States of the Organisation africaine de la propriété intellectuelle that are classed as least developed countries to adopt TRIPS before the requisite policy, legal and regulatory frameworks have been finalized.

In addition to the general finding of lack of TRIPS compliance, it was also pointed out in the 2013 report that SADC member States were yet to make full use of the flexibilities available to them under TRIPS, notwithstanding continuing efforts and technical assistance from the United Nations Development Programme and other United Nations agencies to achieve this (see, for example, Botswana (2013)). The harmonization of intellectual property rights systems at the regional level was also recommended in the 2013 report. “Such harmonization will improve the flow of investment, technology transfer, as well as contribute to the orderly development of the world economy. This can be achieved through ... updating ... intellectual property legislation and alignment to TRIPS guidelines and domestication of the African Regional Intellectual Property Organization framework” (United Nations, 2015, p. 42). Emphasis was on TRIPS compliance and on taking advantage of the TRIPS flexibilities, modernization and harmonization of intellectual property policies.

The present study is intended to begin the process of implementing these recommendations, with the dual limitation that the domestication of the African

⁸ World Trade Organization. Council for Trade-Related Aspects of Intellectual Property Rights. Decision IP/C/64 of 11 June 2013 on extension of the transition period under article 66.1 for least developed country members. For an overview of the genesis and extent of the original extension period and the latest extension request made in 2012, see Abbott (2013).

Regional Intellectual Property Organization framework is pertinent only to its member States and that least developed countries are not yet required to comply with TRIPS.

B. Study objectives and scope

The overall objective of the present study is to develop a harmonized and internationally compliant regional framework on intellectual property rights for SADC member States. The regional framework will include templates for policies, legislation and proposals for the required infrastructure for intellectual property rights. Furthermore, the harmonized regional framework will be supported and underpinned by proposals for a common approach to international cooperation in intellectual property rights. In addition, this study is intended to explore issues of patent-related flexibilities.

The study contains an investigation of the following:

- a) National, regional and international best practice in intellectual property rights frameworks, identifying elements for adaptation;
- b) The intellectual property rights landscape in SADC member States, identifying strengths and weaknesses and alignment to international norms;
- c) The level of harmonization of policies, legislation and intellectual property rights infrastructure;
- d) The existing regional cooperation framework on intellectual property rights.

The study contains recommendations for a framework for regional cooperation on intellectual property; outlines the development of an intellectual property policy template for adaptation by member States and a template for national legal and regulatory frameworks and national infrastructure for intellectual property rights; and a road map for the domestication of the templates and recommendations on how SADC member States could exploit TRIPS flexibilities.

C. Methodology and limitations

The primary methodology of study was desk research, which relied on secondary data and information in the public domain, mostly from Internet sources. The time frames for the completion of the research did not permit the effective use of questionnaires addressed to national intellectual property institutions for data collection. The study was accordingly limited to a desk review of published information. The review and verification was constrained because not all SADC member States maintain official websites relating to intellectual property that archive all relevant laws and other documentation (where such websites exist, they do not all contain updated information on IP) and not all SADC member States have submitted their intellectual property laws and related documents to WIPO or WTO for archiving in their online repositories.

Nevertheless, the validation meeting for this report held in Johannesburg from 20 to 22 March 2017 also provided an opportunity to verify some of the information and update sections of the report.

D. Structure of the report

The report consists of four chapters following this introduction. Chapter 2 contains a consideration of national, regional and international frameworks, with a view to distilling best practices for the regional member States. Chapter 3 is focused on intellectual property protection in the SADC region to identify the status quo and pinpoint areas for reform in the alignment process. In particular, it provides a review of policy and legislative frameworks; TRIPS compliance for developing countries; and the levels of cooperation on intellectual property and harmonization of intellectual property policies and governing structures among member States. Chapter 4 contains a discussion of the use of flexibilities by SADC member States, an area in which action is required as the region moves towards harmonization. Chapter 5 concludes the report with a summary of recommendations, including actions towards harmonization of intellectual property policies, laws and governance structures. Two annexes are appended, providing for practical approaches to implementing these recommendations through templates and road maps for the various aspects.

Chapter 2: National, regional and international best practice in intellectual property rights frameworks

A. Introduction

This chapter contains an overview of national, regional and international frameworks on intellectual property rights, and identifies relevant elements for adaptation by SADC member States in the process of harmonizing their frameworks. The overview looks beyond the SADC region for experience and best practice in intellectual property rights, drawing on a variety of regional and international experience to make appropriate recommendations for the SADC region.

B. National frameworks

In general, national intellectual property frameworks consist of policies, laws and attendant administrative and enforcement structures. An ideal national intellectual property framework consists of a domestic policy, regulatory instruments, administrative structures or mechanisms and clearly articulated enforcement mechanisms.

A clear and detailed intellectual property policy serves as a blueprint of a country's approach to intellectual property by specifying what the policy's goals and objectives are. It also specifies how these may best be achieved in a way that enhances or aids the attainment of national developmental goals. This is because the purpose of laws is "to give legal effect to a government policy decision for deliberate change to address a social, economic or political need". To achieve its policy objectives, the national law has to be of a specific quality (Aitken, 2013). In general, it is accepted that legislation of quality should exhibit the characteristics outlined in box 1.

Thus, a good intellectual property legislative framework would cover all relevant aspects of intellectual property in a way that is compliant with international standards, the relevant State's constitution and other relevant laws or policies. In addition to international treaties, it should also be compliant with any binding regional and subregional agreements (harmonization). The law should be drafted so

Box 1: Characteristics of quality legislation

- Legality, conformity with the constitution, international treaties and the effectuation of general legal principles
- Effectiveness and efficiency
- Subsidiarity and proportionality
- Practicability and enforceability
- Harmonization
- Simplicity, clarity and accessibility.

that it can meet its goals (effectiveness) and do so in the most direct and sensible manner (efficiency). The sanctions that it provides for should be appropriate for the wrongdoing in question (proportionality). This body of laws ought to be well drafted and easy to both understand and implement, making it simple, clear and accessible. Substantively, it ought to attain the ideal of serving the public interest and avoid favouring any group of intellectual property stakeholders at the expense of others (Ncube, 2013, pp. 370 and 372). The regulatory and policy framework needs to be efficiently administered by a competent authority that is adequately staffed with appropriately qualified personnel (practicability) (United Nations, 2015, pp. 38-39). Owing to the cross-cutting nature of intellectual property, which implicates various government departments, an intentional approach to interministerial coordination needs to be in place (domestic harmonization) (Ibid., p. 35). Furthermore, there need to be meaningful enforcement avenues to which right-holders can resort to protect their rights (enforceability). Such enforcement mechanisms will extend to the existence of adequate border control measures (Ibid., p. 38).

There are various indices that are intended to evaluate and then rank national intellectual property frameworks. Examples of well-known indices include the annual International Property Rights Index⁹ of the Property Rights Alliance and the Ginarte and Park Index (Park (2008) pp. 761–766; Ginarte and Park (1997), pp. 283–301) on patent rights. Considering their evaluative criteria will provide insight into the key elements that a sound or ideal national framework ought to incorporate. Both these indices consider the following in relation to patents: coverage, membership in international treaties, restrictions on patent rights, enforcement and duration of protection (Di Lorenzo, 2013, pp. 16-20, for much of this paragraph). The Alliance considers industry-sourced and published data on copyright piracy. This is, however, a questionable approach because an inherent right-holder perspective may compromise such data. Although it is a useful gauge of a country's intellectual property performance, it has to be applied cautiously. At the lowest level of analysis, one may say that an ideal national intellectual property framework is one that is fully compliant with international intellectual property standards and is simultaneously appropriately adapted to be aligned with national developmental goals. Bearing in mind the above caution about non-discerning reliance on the International Property Rights Index, it is instructive to consider which developing countries rank highly on this Index and to briefly summarize the peculiar elements of their intellectual property regimes.

According to the 2013 International Property Rights Index, South Africa is the highest-ranked African country, with an intellectual property rights score of 7.5 of a possible maximum of 10 (Di Lorenzo, 2013, p. 20). It is instructive to compare this with the other nations in the Brazil-Russia-India-China-South Africa (BRICS) bloc. Brazil has an intellectual property rights index of 5.6, Russia 4.9, India 5.5 and China scores 5.4. Although South Africa's intellectual property system is much stronger than those of its fellow bloc countries, they have received substantially higher inflows of foreign direct investment (FDI) than South Africa.¹⁰ David Kaplan (2009) argues that this may imply that, while intellectual property frameworks are important, there

⁹ See <http://internationalpropertyrightsindex.org>.

¹⁰ United Nations Conference on Trade and Development (2011a), p. 3, notes that, in 2010 South Africa received \$1.3 billion in inflows of foreign direct investment, while Brazil received \$30.2 billion, China received \$101.1 billion (exclusive of the financial sector), India received \$23.7 billion and Russia received \$39.7 billion.

are other factors that have a stronger impact on FDI decisions than the intellectual property rights index. There is therefore no direct correlation between the strength of an intellectual property system and inflows of FDI, as argued by several scholars (Kashcheeva (2013); Ncube (2013); Maskus (1998), pp. 109 ff.; Yu (2008), p. 153) and a 2006 United Nations Industrial Development Organization study (Falvey, Foster and Memedovic, 2006). In view of its high ranking, it is instructive to review the South African policy framework to isolate elements that could inform the SADC regional policy and legal framework on intellectual property.

1. South Africa's national framework on intellectual property

South Africa has a policy framework for the protection of indigenous traditional knowledge through the intellectual property system (South Africa, 2008) and a draft national intellectual property policy, which was first published for comment in 2013.¹¹ In 2016, the Department of Trade and Industry published a consultative framework on intellectual property to facilitate further engagement on the draft policy (South Africa, 2016). The purpose of the draft national intellectual property policy is “to argue for the policy to talk to other relevant national policies and international agreements that advance the aspirations of a developing nation and to coordinate the national and international approaches on various intellectual property matters”.¹² It consists of 17 chapters which address various aspects of intellectual property, including intellectual property and public health (chapter 2); agriculture and genetic resources (chapter 3); intellectual property and indigenous knowledge (chapter 4); and intellectual property and development (chapter 10). Several recommendations that pertain to institutional reform are made by the policy, such as the introduction of substantive examination of patents, legislative reform and outreach or awareness-raising initiatives.

South Africa's intellectual property legislation is informed by the policy on traditional knowledge, as evidenced by the amendment of patent, copyright and design legislation in 2013 through the Intellectual Property Laws Amendment Act.¹³ In addition, the country has established a national recordal system for indigenous knowledge, which serves as an important depository and provides some protection for this knowledge. The Department of Science and Technology introduced the Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill to Parliament on 12 April 2016.¹⁴

Once the draft national intellectual property policy is finalized, it is expected that intellectual property legislation will be amended, in line with its precepts. Another policy document is the country's intellectual property rights from publicly financed research framework of 2006, which led to the Department of Science and Technology's 10-year innovation plan of 2008 and culminated in the enactment of the Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008

11 Government Gazette No. 36816 of 4 September 2013, General Notice No. 918.

12 Draft policy, p. 9.

13 Intellectual Property Laws Amendment Act 2013 (Act No. 28 of 2013). Available from www.wipo.int/wipolex/en/details.jsp?id=13714 (accessed 14 November 2017).

14 Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill, B6-2016.

Table 1: Core intellectual property legislation in South Africa

Intellectual property rights	Legislation
Patents	Patents Act 57 of 1978
Copyright and related rights	Copyright Act 98 of 1978
	Performers Protection Act 11 of 1967
	Registration of Copyright in Cinematograph Films Act 62 of 1977
Trademarks	Trademarks Act 194 of 1993
Designs	Designs Act 195 of 1993
Sui generis	Plant Breeders Rights Act 15 of 1976
Publicly funded research	Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008
Border control/enforcement	Counterfeit Goods Act 37 of 1997

Source: Compiled by the author.

and its 2009 Regulations.¹⁵ This Act is currently under review and may be amended for alignment with the finalized policy. South Africa has a plethora of other intellectual property and related legislation,¹⁶ and table 1 provides the basic framework of the core South African intellectual property legislation. States in the SADC region that are not yet in a position to implement such legislation have the option of initial reliance on policy, accompanied by structures to provide resources such as an Innovation Fund.

The interface between patents and access to medicines and the protection of traditional knowledge are among the controversial aspects of South Africa's intellectual property regime. Although section 56 of the Patents Act provides for compulsory licences and section 15C of the Medicines and Related Substances Control Act makes provision for parallel imports, there is still dissatisfaction about the manner in which patents affect access to medicines.¹⁷ In particular, perceived weaknesses pertain to the country's patent registry or depository system. The grant of patents without substantive examination allows practices such as "evergreening" to continue uncurbed. It has been suggested that the country should consider various ways of introducing patent examination so as to strengthen its system (Ncube, 2014, pp. 822-829). It has also been suggested the country's definition of "inventive step" be revised upwards so as to make it difficult, if not impossible, to evergreen patents (Park, Prabhal and Berger (2013); Vawda (2014), p. 305). These and other flexibilities are discussed in chapter 4.

As noted above, South Africa has recently amended its legislation in order to provide for the protection of traditional knowledge.¹⁸ This approach has been criticized for forcing traditional knowledge into conventional intellectual property protection instead of crafting a completely sui generis approach that would ensure that the broad issues around traditional knowledge are covered. South Africa's slant is therefore at variance with the African Regional Intellectual Property Organization approach in

¹⁵ For a study of this legislation and its impact see Ncube, Abrahams and Akinsanmi (2014), pp. 282-315.

¹⁶ See a listing on the World Intellectual Property Organization's WIPO Lex website: www.wipo.int/wipolex/en/profile.jsp?code=ZA (accessed 23 August 2017).

¹⁷ As exemplified by the Treatment Action Campaign's "Fix the Patent Laws" campaign.

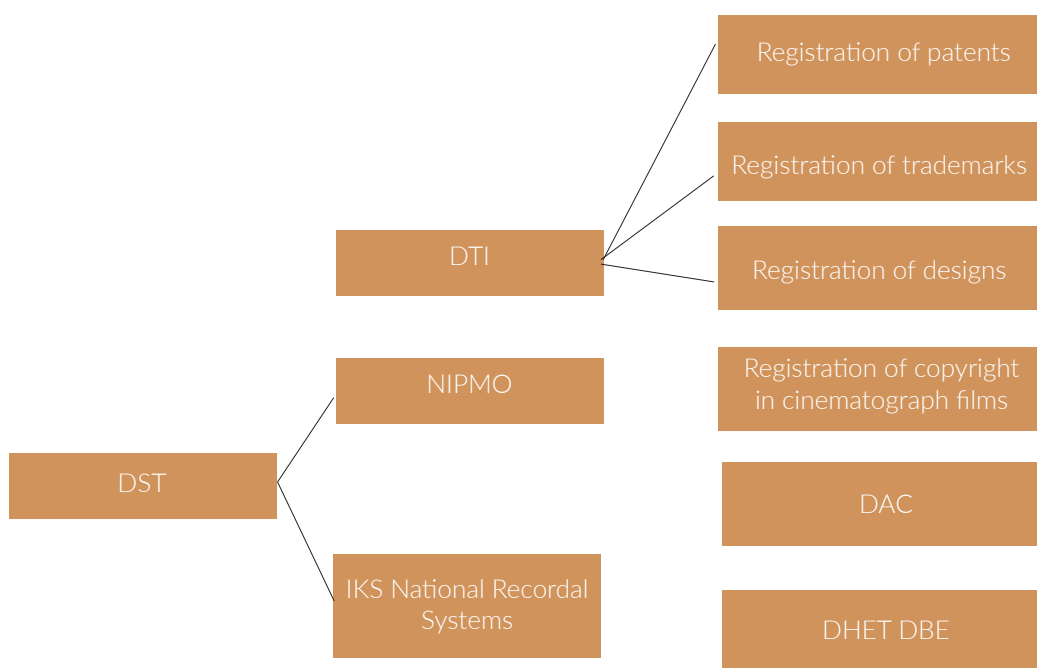
¹⁸ For a discussion of the relevant Amendment Act, see Van der Merwe (2014), p. 417; Ncube (2015).

the Swakopmund Protocol,¹⁹ to which several SADC member States have subscribed (Nkomo, 2013b). South Africa's Indigenous Knowledge Systems Bill, 2016, is intended to introduce a sui generis approach.²⁰

The country's intellectual property administration system operates out of the Companies and Intellectual Property Commission, a division of the Department of Trade and Industry. This department is the lead intellectual property department, although the Departments of Health, Science and Technology, Higher Education and Training, Basic Education and Arts and Culture are also involved, to a lesser extent, with intellectual property matters. Depending on the issues at stake, each department may play a prominent role. For example, the Department of Health is heavily involved in relation to policy on patents and access to medicines. Likewise, when it comes to copyright and the cultural industries, the Department of Arts and Culture may be more involved. In the same way, the Department of Science and Technology led the way in relation to intellectual property rights and publicly funded research. The Department of Higher Education and Training published a white paper on post-secondary education that promotes the use of open educational resources and more effective use of distance education. Similarly, the Department of Basic Education ought to be heavily invested in copyright policy and law, given that it affects access to learning materials.

When it comes to actual administration of intellectual property rights, the Companies and Intellectual Property Commission registers patents, trademarks, designs and copyright in cinematograph films. The Department of Science and Technology's Technology Innovation Programme houses the National Intellectual Property Management Office, which has oversight of compliance with the Intellectual Property Rights from the Publicly Funded Research Act. In addition, the Department of Science and Technology's National Indigenous Knowledge Systems Office is cooperating with

Figure 1: South Africa's intellectual property administration infrastructure



¹⁹ For commentary, see Ngombe (2011).

²⁰ For a detailed discussion of the country's attempts to protect traditional knowledge, see Ncube (2016), p. 29.

the Meraka Institute of South Africa's Council for Scientific and Industrial Research in running the country's Indigenous Knowledge Systems National Recordal System. These administrative functions are illustrated in figure 1.

The Departments of Arts and Culture, Higher Education and Training, and Basic Education do not perform any intellectual property administration or registration. Their key mandates, however, are affected by intellectual property law, in particular the law on copyright, which protects a significant portion of the creative and academic or educational materials that are created or used by their key stakeholders. The 2016 consultative framework on intellectual property contains a proposal for the creation of an interministerial committee composed of "government officials responsible for implementing programmes that either affect or are affected by IP" to streamline the process and lay the platform for harmonization. The committee would also "work closely with government officials representing South Africa at multilateral forums to ensure harmonized negotiating positions" (South Africa, 2016).

There are many progressive and innovative features in the South African system that could inform the ongoing regional processes, and South Africa's international ranking in some intellectual property rights indices confirms the recognized high level of development of the intellectual property system. SADC member States could consider the relevant strong points in the South African system in crafting a regional framework and harmonizing intellectual property rights.

C. Intellectual property frameworks in relevant regional economic communities and intergovernmental organizations

As a regional intellectual property framework is argued for, it is also instructive to examine the approach followed in regional economic communities in dealing with intellectual property issues. As shown in table 2, some SADC member States are also members of one or more of the following: COMESA, the East African Community, the Indian Ocean Commission and the Southern African Customs Union. Within the spirit of harmonization and regional integration, the frameworks in these organizations should be aligned in the medium to long term.

Some of these regional economic communities have a common approach to intellectual property and, in specific cases, a common intellectual property regime. It is important to emphasize that African States intend to create an African economic community by 2028.²¹ As a precursor, COMESA, the East African Community and SADC have agreed to form a tripartite free trade area (United Nations, 2011, p. 5). Furthermore, African countries have committed themselves to establishing a continental free trade area by 2017. It has been proposed that the tripartite free trade area should merge with the Economic Community of West African States as a first step towards establishing the continental free trade area (Ngwenya, 2015). The move towards the conclusion of a series of framework agreements that would cater for some aspects such as intellectual property and competition within the continental free trade area

²¹ Abuja Treaty Establishing the African Economic Community, 1991, article 6, paragraph 1. The treaty entered into force in 1994, and this article provides for the creation of the community within a maximum of 34 years.

Table 2: SADC member States' membership of other regional economic communities and intergovernmental organizations

SADC member States	COMESA	EAC	ECCAS	IOC	SACU
Angola	X		X		
Botswana					X
Democratic Republic of the Congo	X		X		
Eswatini	X				X
Lesotho					X
Madagascar	X			X	
Malawi	X				
Mauritius	X			X	
Mozambique					X
Namibia					
Seychelles	X			X	
South Africa					X
United Republic of Tanzania		X			
Zambia	X				
Zimbabwe	X				

provides a good platform for harmonization. It is therefore important to ensure that any SADC initiatives to harmonize the treatment of intellectual property are aligned to the COMESA-East African Community-SADC intellectual property agenda, and to potential frameworks for the continental free trade area, as well as to the ultimate aim of establishing the African Economic Community. Furthermore, given the membership of some SADC member States in the Indian Ocean Commission and the Southern African Customs Union, it will be important to ensure that cognizance is taken of the frameworks in these regions.

The following section will outline the intellectual property frameworks of COMESA and the East African Community in view of the significance of the tripartite agenda. It will also briefly outline the framework of the Southern African Customs Union and what is obtaining in the Indian Ocean Commission.

The COMESA member States are Burundi, Comoros, the Democratic Republic of the Congo, Djibouti, Egypt, Eritrea, Eswatini, Ethiopia, Kenya, Libya, Madagascar, Malawi,

Mauritius, Rwanda, Seychelles, the Sudan, Uganda, Zambia and Zimbabwe. As shown in table 2, eight of these countries are also SADC member States. The regulatory framework of COMESA for intellectual property consists of the following provisions:

Article 104(1)(d) of the COMESA Treaty²² provides for information-sharing on “legislation on patents, trademarks and designs”. Further, article 128(e) provides that:

“In order to promote cooperation in science and technology development, the member States agree to jointly develop and implement suitable patent laws and industrial licensing systems for the protection of industrial property rights and encourage the effective use of technological information contained in patents”.

COMESA has adopted several protocols, policies and strategies, including the COMESA Regional Policy on Intellectual Property Rights and Cultural Industries (COMESA, 2013) (table 3).

²² Treaty Establishing the Common Market for Eastern and Southern Africa (1994).

Table 3: Common Market for Eastern and Southern Africa policy structure on intellectual property

Part A	Part B: The Common Market for Eastern and Southern Africa policy on copyright and copyright-related industries
Introduction	Introduction
Overview of intellectual property	Situation analysis
Opportunities created by intellectual property	Policy objectives
Intellectual property and economic development	Applicability
Intellectual property and trade	Benefits
Intellectual property and cultural industries	Role of the Common Market for Eastern and Southern Africa secretariat
Intellectual property and traditional knowledge and expressions of folklore	Copyright
Intellectual property and information and communications technology	Publishing
Intellectual property audit and valuation	Media and advertising
Copyright and related rights	Computer software
Industrial property	Music
	Film
	Theatre and performing arts
	Collective management organizations
	Expressions of traditional cultural expressions
	Valuation of copyright
	Legal framework
	Commercialization of copyright works

This policy is a detailed statement of the COMESA member States' commitment to regulating and implementing intellectual property in a specific manner. Among other undertakings, the member States agree to encourage each other "to utilize and exploit to the full the flexibilities provided in ... international treaties [on IP] such as the Doha Declaration on the TRIPS Agreement and Public Health so as to facilitate access to medicines for all people particularly the marginalised of society" (ibid., part A, para. 39(d)) and to "promote harmonization of industrial property legislation within COMESA in view of the establishment of the customs union" (ibid., para. 39 (e)). In relation to copyright, the main policy objective is to "encourage and promote copyright protection for socioeconomic development within the COMESA member States, recognizing that copyright is a major component of intellectual property" (ibid., part B, para. 8). There is no mention, however, of using available flexibilities in the context of industrial property to achieve public interest goals such as education or access to knowledge.

COMESA received technical assistance from WIPO in the finalization of this policy.²³ In 2011, COMESA finalized guidelines for preparing national policy on intellectual property in accordance with this regional policy.²⁴ Although the guidelines document is not currently publicly available for evaluation of its contents, the principle of

²³ World Intellectual Property Organization, Technical Assistance Database: Activity Details. Available from www.wipo.int/tad/en/activitydetails.jsp?id=2283. WIPO Technical Assistance Database: Activity Details. Available from www.wipo.int/tad/en/activitydetails.jsp?id=2246 (accessed 14 November 2017).

²⁴ Common Market for Eastern and Southern Africa, Council of Ministers Decision 90(f), Official Gazette of COMESA, vol. 16 (15 October 2011); COMESA, Report of the Thirtieth Meeting of the Council of Ministers CS/CM/XXX (2 October 2015), para 249.

developing guidelines to assist member States in domesticating a regional intellectual property policy is commendable and provides important lessons for the regional efforts in SADC. As will be shown in the next chapter, however, most SADC member States are already working individually on national intellectual property policies, so it is important to formulate a regional framework to guide their work on intellectual property policy. In addition, SADC will be guided by the annex on intellectual property rights to the agreement on a Tripartite Free Trade Area (COMESA-East African Community-SADC), which is almost indistinguishable from the COMESA intellectual property policy.

The full membership of the East African Community is Burundi, Kenya, Rwanda, the United Republic of Tanzania and Uganda. The East African Community Treaty²⁵ contains provisions on intellectual property in articles 75, 103 (1) (i) and 112 (2) (n), namely:

Article 75: Establishment of a customs union.

Article 103 (1) (i): Recognizing the fundamental importance of science and technology in economic development, the Partner States undertake to promote cooperation in the development of science and technology within the Community through: the harmonization of policies on commercialization of technologies and promotion and protection of intellectual property rights.

Article 112 (2) (n): ... the Partner States undertake to adopt common policies for conservation of biodiversity and common regulations for access to, management and equitable utilization of genetic resources.

In addition, the East African Community has adopted a range of protocols, policies and strategies, as shown in table 4.

²⁵ Treaty for the Establishment of the East African Community, adopted on 30 November 1999 at Arusha. Available from www.wipo.int/edocs/lexdocs/treaties/en/eac/trt_eac.pdf.

Table 4: East African Community protocols, policies and strategies

Protocol on the Establishment of the East African Customs Union
Protocol on the Establishment of the EAC Common Market
Protocol on the Establishment of the East African Monetary Union
East African Community Industrialization Policy 2012–2032
East African Community Industrialization Strategy 2012–2032
East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012–2016)
Poverty Impact Assessment of the East African Community Regional Pharmaceutical Plan of Action
East African Community Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation
East African Community Communication Policy and Strategy
East African Community Consultative Dialogue Framework

The East African Community also published a draft policy on anti-counterfeiting, anti-piracy and other intellectual property rights violations and a draft anti-counterfeit bill in 2010. These were, however, not adopted for a variety of reasons.²⁶ East African Community member States also introduced draft anti-counterfeiting legislation²⁷ which became law in Kenya²⁸ and the United Republic of Tanzania.²⁹ The definition of “counterfeit” in the Kenyan legislation, however, was struck down by the High Court because it was overly broad and included generic medication.³⁰ Given that the Government did not appeal against this decision, the definition section and other relevant sections of the Act “cannot be enforced insofar as they affect access to affordable and essential medicines” (Nyachae and Ogendi, 2012, p. 14).

Of the protocols, policies and strategies in table 4, the policy of relevance to this study is the Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation. It is based on an analysis of the East African Community partner States’ national legislation and is aimed at assisting these States to domesticate and implement TRIPS flexibilities meaningfully. To this end, it makes the 11 policy statements that are detailed in chapter 4.

COMESA, the East African Community and SADC reached agreement on the establishment of a tripartite free trade area in October 2008 (United Nations, 2011, p. 5). Article 27 of the tripartite agreement provides that:

- a) Tripartite member States shall protect intellectual property rights in a balanced manner that promotes the social economic welfare of society through ensuring that the people of the region meaningfully benefit from

26 See, for example, Regional Network for Equity in Health in East and Southern Africa (EQUINET) (2010); Musungu (2010).

27 Kenya - the Anti-Counterfeit Bill (2008); Uganda - the Counterfeit Goods Bill (2010); United Republic of Tanzania – the Merchandise Marks Act, 1963, and subsidiary legislation.

28 Anti-Counterfeit Act, Act No. 13 of 2008.

29 2008 Merchandise Marks Regulations, adopted under section 18A of the Merchandise Marks Act, 1963, and further Merchandise Marks (Amendments) Regulations, 2010.

30 Patricia Asero Ochieng, Maurine Atieno and Joseph Munyi v The Attorney General HCCC Petition No. 409 of 2009 Para 78. For commentary on the case see Maleche and Day (2014); Nyachae and Ogendi (2012); Durojaye and Mirugi-Mukundi (2013).

Table 5: Common Market for Eastern and Southern Africa-East African Community-Southern African Development Community annex B provisions on intellectual property rights

COMESA-EAC-SADC Annex B provisions
Art 1: Trade and development
Art 2: Trade negotiations
Art 3: Cultural and creative industries
Art 4: Traditional knowledge
Art 5: Information and communications technology
Art 6: Copyright
Art 7: Industrial property
Art 8: intellectual property audits

and participate in advancements in the arts and science and technology in accordance with annex 9 on intellectual property rights;

- b) Tripartite member States shall adopt policies on intellectual property rights, including the protection and promotion of cultural industries in accordance with international agreements;
- c) Tripartite member States shall cooperate and develop capacity to implement and utilize the flexibilities in all relevant international agreements on intellectual property rights.

Annex 9 of the COMESA-East African Community-SADC tripartite agenda provides the required detail (table 5).

As a member of the COMESA-East African Community-SADC tripartite grouping, SADC has regional policy guidance on intellectual property in the form of the tripartite treaty's annex on intellectual property, which should be taken into account in developing a framework for SADC. The Sharm El Sheikh declaration launching the COMESA-East African Community-SADC tripartite free trade area was signed on 10 June 2015, and negotiations on matters relating to intellectual property will proceed as a second stage to this development (Ncube, 2016a, p. 86).

As shown in table 2, the Southern African Customs Union member States are Botswana, Eswatini, Lesotho, Namibia and South Africa. Article 18 of the 2002 Agreement provides as follows:

Free movement of domestic products

1. Goods grown, produced or manufactured in the Common Customs Area, on importation from the area of one member State to the area of another member State, shall be free of customs duties and quantitative restrictions, except as provided elsewhere in this Agreement.

2. Notwithstanding the provisions of paragraph 1 above, member States shall have the right to impose restrictions on imports or exports in accordance with national laws and regulations for the protection of (a) health of humans, animals or plants; (b) the environment; (c) treasures of artistic, historic or archaeological value; (d) public morals; (e) intellectual property rights; (f) national security; and (g) exhaustible natural resources.

The Southern African Customs Union has not adopted any protocols, policies or strategies that directly regulate intellectual property. In 2006, a free trade agreement was concluded³¹ between the Southern African Customs Union and the European Free Trade Association.³² Article 1 of this agreement lists objectives, which include the promotion of adequate and effective protection of intellectual property rights (art. 1 (c)). Article 26 (2) of the agreement provides that “the parties shall grant and ensure adequate, effective and non-discriminatory protection of IP rights, and provide for measures for the enforcement of such rights against infringement thereof, counterfeiting and piracy, in accordance with the provisions of this article and the obligations set out in the international agreements to which they are parties”. There is also provision for national treatment (art. 26 (3) and (4)). The member States of the Association also undertook to provide Southern African Customs Union member States with “regulatory assistance and implementation of laws in areas such as services, investment, intellectual property and public procurement” (art. 32 (2) (e)).

In 2008 the Southern African Customs Union entered into a preferential trade agreement with the Southern Common Market³³ that does not substantively regulate intellectual property. Similarly, its cooperative agreement on trade, investment and development with the United States of America, also concluded in 2008, does not substantively regulate intellectual property. In its preamble, “the importance of providing adequate and effective protection and enforcement of intellectual property rights in accordance with international standards and of membership in and adherence to intellectual property rights conventions” is merely recognized.

The Indian Ocean Commission is an intergovernmental organization established in 1982 in Port Louis. It was operationalized in 1984 by the Victoria Agreement. Its member States are the Comoros, Madagascar, Mauritius, Reunion and Seychelles. The Commission’s regional integration programme does not yet extend to intellectual property matters (African Development Bank, 2012).

D. Summary and conclusion

In this chapter, the importance of a national architecture for intellectual property underpinned by a policy, regulatory instruments, administrative structures and enforcement mechanisms has been emphasized and the key elements of each discussed.

31 World Trade Organization, Trade Policy Review – Southern African Customs Union – report by the secretariat. Document WT/TPR/S/222 (30 September 2009), p. 14.

32 The members of the Association are Iceland, Liechtenstein, Norway and Switzerland.

33 The members of Mercosur are Argentina, Brazil, Paraguay, Uruguay and Venezuela (Bolivarian Republic of).

The national intellectual property framework for South Africa has been presented as a potential model for SADC member States. This section is based both on the 2013 report published by ECA and the SADC secretariat (United Nations, 2015), in which South Africa was identified as having one of the best-structured frameworks among SADC member States, and the fact that South Africa is highly ranked in the index published by the Property Rights Alliance. South Africa is yet to finalize its intellectual property policy, notwithstanding extensive consultations.

The regulatory frameworks of COMESA, the East African Community and the Southern African Customs Union with regard to intellectual property were outlined above, as was the COMESA-East African Community-SADC tripartite intellectual property agenda. Of the three regional blocs, the Southern African Customs Union has the least substantive regulation of intellectual property. The East African Community has adopted very detailed provisions on the appropriate use of TRIPS flexibilities by least developed countries, which will be discussed in chapter 4. The intellectual property policy of COMESA and the “Annex on intellectual property” of the intellectual property agenda of the tripartite free trade area document provide detailed guidance on an appropriate policy direction for developing countries. SADC is associated with these precepts by virtue of its participation in the tripartite agenda, and any regional framework on intellectual property that it creates must be aligned with this policy direction. A commendable COMESA practice is that of preparing guidelines to assist member States in preparing their own national policies on intellectual property.

Chapter 3: Protection of intellectual property rights in the Southern African Development Community region

A. Introduction

The joint ECA-SADC study referred to above (United Nations, 2015) contains a comprehensive overview of the national intellectual property rights frameworks of SADC member States. The present report will simply provide a summary of the state of intellectual property protection in SADC member States (and update the information where changes have occurred) in order to highlight possibilities for regional harmonization and cooperation. This summary will focus on a number of points of comparison, as detailed in box 2:

Box 2: Comparison basis for intellectual property frameworks

- National intellectual property policies
- National intellectual property legislation
 - Industrial property legislation
 - Legislation on copyright and related rights
 - Compliance of this legislation with TRIPS, for those countries that are not covered by the compliance transition period
- Intellectual property administration infrastructure
- The use of TRIPS flexibilities in national legislation

The discussion in this chapter will consider the first two points (and three subpoints) contained in box 2, while the last point will be the subject of chapter 4.

B. National policies on intellectual property

The existence of an intellectual property policy is indicative of a country's attempts to take a strategic and harmonized approach to intellectual property. Intellectual property policies provide a blueprint that can guide various national departments and agencies in relation to intellectual property. Many developing countries have recently begun drafting policies with a view to aligning intellectual property and developmental goals more closely. A policy may be used to inform legislative amendments once it is in place.

Many SADC member States have formulated their intellectual property policies with technical assistance from WIPO (Ncube, 2016a, pp. 46-50). The terms of engagement in such technical assistance endeavours are contained in a document known as an “Intellectual property development plan”. The preparation of such a plan indicates that work has begun on creating a policy on intellectual property. WIPO has developed a toolkit for the production of intellectual property strategies under project DA_10_05, “Improvement of national, subregional and regional intellectual property institutional and user capacity”. The project was initially targeted at and piloted in Algeria, the Dominican Republic, Mali, Mongolia, the Republic of Moldova and the United Republic of Tanzania. WIPO published the toolkit in 2014, and it was made available to all countries. The toolkit has four components (tools): tool 1, the process; tool 2, baseline questionnaire; tool 3, benchmarking indicators (World Intellectual Property Organization, 2014a-c); and tool 4, national intellectual property strategies online survey.³⁴

The toolkit was published at a time when many SADC member States and other developing countries had already been the recipients of technical assistance for policy formulation from WIPO. It is not clear whether the organization used the toolkit in all instances of such technical assistance.

The following section outlines which countries already have intellectual property policies or are currently formulating policies. It also indicates which States benefited from technical assistance from WIPO. Draft policies are not covered, given that they may change prior to being finalized and formally adopted. The discussion first focuses on the SADC member States classified as “least developed countries” and then covers the States classified as “developing countries” to discern any commonalities and peculiarities.

a. Least developed countries

Angola: No policy in existence and no publicly available information about the preparation of a policy.

Democratic Republic of the Congo: No policy in existence and no publicly available information about the preparation of a policy.

Lesotho: The national intellectual property policy is currently under formulation, with technical assistance from WIPO (World Intellectual Property Organization, 2013) and the guidance of an interministerial committee (World Trade Organization, 2009b, p. 153). Drafts of this policy have been prepared (United Nations, 2015, p. 25), but are not publicly available.

Madagascar: WIPO reports that it has provided “technical advice for conducting national intellectual property audits” in countries, including Madagascar, as a step towards the creation and adoption of a national intellectual property policy that will “mainstream” intellectual property as an integral part of national planning (World Intellectual Property Organization, 2013). In February 2013, Madagascar submitted a request for technical and financial assistance from WTO for the “development of a

³⁴ Available from www.wipo.int/ipstrategies/en/methodology/nips_survey.html.

national IP policy and a legislative framework for IP rights" that would be compatible with the framework of Madagascar's National Cultural Policy Law (World Trade Organization, 2013b). WIPO further reports that Madagascar has included intellectual property considerations specific to least developed countries in its draft national policy on intellectual property (World Intellectual Property Organization, 2014d). It is not possible, however, to ascertain whether the policy is in draft or final form, because this document is not publicly available and the author has not seen it.

Malawi: A draft policy on intellectual property has been prepared, with technical assistance from WIPO. It awaits Cabinet approval (Zakeyo-Chatima, 2011). The WIPO Regional Bureau for Africa has hosted a number of workshops and meetings on Malawi's intellectual property policy. It also hosted a meeting convened to review the draft national intellectual property policy and discuss the formulation of a national intellectual property strategy, as well as the organization of a national policy meeting on the strategic use of intellectual property for technological capacity-building, economic growth and development in October 2013.³⁵

Mozambique: Mozambique developed its intellectual property strategy for the period 2008-2018 with technical assistance from WIPO (World Intellectual Property Organization, 2010b). The strategy is structured as follows:

- a) Overview of intellectual property in Mozambique;
- b) Importance of intellectual property;
- c) Vision and goals;
- d) Strategic framework and strategic areas;
- e) Dissemination of intellectual property;
- f) Education and intellectual property;
- g) Scientific and technological research;
- h) Innovation and competitiveness in industry;
- i) Traditional knowledge and biodiversity;
- j) Creativity and development of the cultural industry;
- k) Administration of the intellectual property system.

³⁵ World Intellectual Property Organization. Technical Assistance Database - Activity Details. Available from www.wipo.int/tad/en/activitydetails.jsp?id=6400. Accessed 13 January 2015.

An intellectual property action plan is appended to the strategy in annex II. It outlines 25 strategic goals to which short-term and medium-term actions are assigned, as is a mid-term (2012) achievement target. In general, the strategy is well formulated and in line with its stated vision and goals, which are to craft an appropriate intellectual property framework for the country so as to ensure that it achieves its developmental goals. The 2008–2018 strategy document is currently under review in preparation for the production of a document for the period beginning 2019.

United Republic of Tanzania: As mentioned above, the United Republic of Tanzania was one of the six countries for which the WIPO methodology and tools for the development of national intellectual property strategies was developed. At the end of 2014, WIPO reported that it was in consultation with the United Republic of Tanzania in relation to the formulation of its intellectual property strategy and intellectual property policy (World Intellectual Property Organization, 2014d). The Business Registration and Licensing Agency, which administers intellectual property for the mainland, intends to publish an action plan for the development of intellectual property policies for the mainland and for Zanzibar on its website.

Zambia: The country has finalized its intellectual property policy with technical assistance from WIPO (World Intellectual Property Organization, 2013), and an implementation plan was adopted in 2010.³⁶ However, neither of these two documents are publicly available.

b. Developing countries

Botswana: The national competition policy for Botswana (2005) excludes intellectual property from its ambit. The research, science, technology and innovation policy of 2011 states that a national intellectual property policy “needs to be developed”. The national intellectual property development plan for 2012 includes a report on an intellectual property audit and a strategy road map for the development of a national intellectual property policy. At the end of 2014, WIPO reported that it was in consultation with Botswana in relation to the formulation of its intellectual property strategy (World Intellectual Property Organization, 2014d).

Eswatini: It is reported that Eswatini has committed itself to finalizing a national intellectual property policy by 2020 (Dlamini, 2014). To this end, a workshop entitled “National intellectual property policy workshop: the strategic use of intellectual property for technological capacity-building, economic growth and development” was hosted in Mbabane in May 2014.³⁷

Mauritius: Mauritius has an intellectual property development plan formulated in 2009. The plan was prepared with technical assistance from WIPO (World Intellectual Property Organization, 2010b). It is intended “to ensure, amongst others, that the organizations involved in IP enforcement, the potential users and generators of IP have the technical capacity and know-how to use IP as a tool to promote research,

³⁶ Organization for Economic Cooperation and Development. Highlights of the Policy Framework for Investment in Zambia. Paper prepared for the fifth NEPAD-OECD Ministerial Conference, held in Dakar on 26 and 27 April 2011. Available from www.oecd.org/investment/investmentfordevelopment/47662751.pdf.

³⁷ World Intellectual Property Organization, Technical Assistance Database: Activity Details. Available from www.wipo.int/tad/en/activitydetails.jsp?id=6763 (accessed 30 August 2017).

innovation, investment and economic growth” (Mauritius, 2014, p. 3). WIPO reported that Mauritius’s policy on intellectual property had been adopted and was being implemented by the end of 2011 (World Intellectual Property Organization, 2013c, p. 3). Nevertheless, at the end of 2014, WIPO reported that it was in consultation with Mauritius in relation to the formulation of a new policy on intellectual property (World Intellectual Property Organization, 2014d).

Namibia: A national intellectual property strategy for Namibia was validated on 13 April 2016 (Ncube, 2016c).

Seychelles: The country has an intellectual property development plan that was prepared in 2010 and that makes reference to the provision of technical assistance. At the end of 2014, WIPO reported that it was in consultation with Seychelles in relation to the formulation of its intellectual property policy (World Intellectual Property Organization, 2014d).

South Africa: As discussed earlier, South Africa released a draft national intellectual property policy for public comment in 2013. Numerous comments were submitted and the next step is further consultation, prior to the finalization of the policy under the 2016 consultative framework on intellectual property.

Zimbabwe: Zimbabwe has been working on an intellectual property policy with technical assistance from WIPO, and a draft policy has been prepared. It has, however, not yet been published for public comment nor been officially adopted.

From the above summary, SADC member States that are classified as “least developed countries” and “developing countries” may be categorized into the following three groups:

- a) Those that have finalized intellectual property policies;
- b) Those that are in the process of formulating policies;
- c) Those that have not commenced policy development.

Table 6 presents a summary of the findings of the review of national intellectual property policies in the region.

Table 6: Intellectual property policies in Southern African Development Community member States

Country	Intellectual property development plan	Intellectual property policy	Intellectual property strategy	World Intellectual Property Organization technical assistance
Angola				
Botswana			In development	Yes
Democratic Republic of the Congo				
Eswatini		In development		Yes
Lesotho		In development		Yes
Madagascar		In development		Yes
Malawi		Draft	In development	Yes
Mauritius	2009	In development		Yes
Mozambique			2008	Yes
Namibia			2016	Yes
Seychelles	2010	In development		Yes
South Africa		Draft, 2013 + intellectual property consultative framework, 2016		
United Republic of Tanzania		In development	In development	Yes
Zambia		2010		Yes
Zimbabwe		In development		Yes

C. National intellectual property legislation

This section features a discussion of current intellectual property legislation in two categories: laws regulating industrial property and laws regulating copyright and related rights. The findings are presented by dividing countries into two groups: least developed countries and developing countries.

Most SADC member States have a body of laws relating to intellectual property, including consumer protection laws and others that are not discussed in this study. This section indicates the sources of substantive intellectual property laws in order to enable a basic assessment of whether a country's intellectual property laws are TRIPS-compliant. The dates of the enactment and last amendment of intellectual property legislation are given.

Industrial property legislation

The industrial property legislation in each member State is cited in the following section, beginning with the least developed countries. In each case, an attempt is made to outline the key attributes of the legislation.

a. Least developed countries

Angola: There is an omnibus law, Law No. 3/92 on Industrial Property of 28 February 1992, that covers trademarks, patents and designs. This law has been characterized as basic and in need of revision. Such revision should be prefaced by an intellectual property audit and must take into account the country's status as a least developed country. As will be discussed later (in chapter 4), the legislation provides for compulsory licensing but does not provide for exceptions and other flexibilities (United Nations, 2015, p. 23).

Democratic Republic of the Congo: There is an omnibus law, Law No. 82-001 of 7 January 1982 on Industrial Property, which covers geographical indications, industrial designs, industrial property, patents (inventions), trade names, trademarks and undisclosed information (trade secrets). This law predates TRIPs and is thus non-compliant (United Nations, 2015, p. 25). Given that the Democratic Republic of the Congo is a least developed country, such compliance is not yet required.

Lesotho: There is an omnibus law, Order No. 5 of 1989, last amended by Act No. 4 of 1997, which regulates patents, utility models, industrial designs, marks, collective marks, trade names and unfair competition. This law predates TRIPs and is thus non-compliant (United Nations, 2015, p. 25). Given that Lesotho is a least developed country, such compliance is not yet required.

Madagascar: Legislation is as follows and covers trademarks, patents and designs: Ordinance No. 89-019 of 1989, Establishing Arrangements for the Protection of Industrial Property in Madagascar, and Decree No. 92-993 of 1992, Implementing Ordinance No. 89-019 of 1989, as amended by Decree No. 95-057 of 1995.

Malawi: Malawi has the following legislation: Trade Marks Act of 1967, Chapter 49:01, Trade Mark Regulations, 1981, and Merchandise Marks Act of 1966, Chapter 49:04; Patents Act of 1986, Chapter 49:02, and Patents Regulations, 1992; and Registered Designs Act of 1985, Chapter 49:05, and Registered Designs Regulations, 1997. Most of this legislation predates the TRIPs Agreement and is thus non-compliant (United Nations, 2015, p. 27). Given that Malawi is a least developed country, such compliance is not yet required.

Mozambique: Patents, trademarks and designs are regulated by the Industrial Property Code (decree 47/2015), which came into force on 31 March 2016.³⁸ It is important to note that this law is TRIPs-compliant, even though such compliance is not yet required of least developed countries.

³⁸ Mozambique, Código da Propriedade Industrial (aprovado pelo Decreto No. 47/2015 of 31 December 2015).

United Republic of Tanzania: On mainland Tanganyika: Trade and Service Marks Act No. 12 of 1986, Trade and Service Marks Regulations, 2000, Merchandise Marks Act No. 20 of 1963 and Merchandise Marks Regulations, 2008; Patents (Registration) Act of 1994, Chapter 217, incorporating Patents Act No. 1 of 1987 (as amended by Acts No. 13 of 1991 and No. 18 of 1991) and Patent Regulations, 1994; and Ordinance No. 25 of 1936, Cap. 219 (designs). On Zanzibar: the Zanzibar Industrial Property Act No. 4 of 2008 regulates industrial property. The industrial property legislation that is post-TRIPS is compliant with minimum international standards because they apply to least developed countries.

Zambia: Industrial property is regulated by the Patents Act (Chapter 400), the Trade Marks Act (Chapter 40) and the Registered Designs Act (Chapter 402). The 2013 study found that Zambia's laws "are generally not adequate in protecting intellectual property rights" (United Nations, 2015, p. 32).

The above enumeration shows that industrial property legislation exists in all the least developed countries, albeit at different levels of sophistication, with some being TRIPS-compliant and others not. There is significant variance in the character of the national laws on industrial property.

b. Developing countries

Botswana: There is an omnibus law, the Industrial Property Act 2010 (which entered into force on 31 August 2012),³⁹ which covers patents, utility models, industrial designs, layout designs of integrated circuits, marks, collective marks and trade names, geographical indications, unfair competition, traditional knowledge and handicrafts. Botswana is described as possessing "one of the most advanced systems in the region as it has modern legislation and has domesticated regional and international treaties" with "TRIPS-compliant laws and intellectual property offices [that] are semi-autonomous" (United Nations, 2015, p. 24).

Eswatini: Patent, Design and Trade Marks Act No. 72 of 1936; Seed and Plant Variety Act No. 7 of 2000; Patents, Utility Models and Industrial Designs Act No. 6 of 1997; and Trade Marks Regulations of 1989, Trade Marks Act No. 6 of 1981 and Merchandise Marks Act No. 24 of 1937. The 2013 report found that these laws are not yet TRIPS-compliant. Consequently, a new Intellectual Property Act has been published but has not yet come into force (United Nations, 2015, p. 31).

Mauritius: Industrial designs, industrial property and patents are regulated by the Trademarks Patents, Industrial Designs and Trademarks Act 2002 (entry into force 8 August 2002). This law was enacted to secure TRIPS compliance, and the country's intellectual property framework has been described as one of the most progressive. The Layout-Designs (Topographies) of Integrated Circuits Act 2002 and the Geographical Indications Act 2002 have been enacted but are yet to come into force (United Nations, 2015, pp. 27-28).

³⁹ Botswana, Industrial Property Act, 2010 (Act No. 8 of 2010), and Industrial Property Act, 2010 (Date of Commencement) Order, 2012. Statutory Instrument No. 69 of 2012. See Botswana Government Gazette dated 31 August 2012 and associated regulations.

Namibia: Instead of having various statutes dealing separately with patents, trademarks and designs, Namibia has an omnibus piece of legislation, the Industrial Property Act No. 1 of 2012, which came into force on 31 August 2012.⁴⁰ This law is TRIPS-compliant (United Nations, 2015, p. 29).

Seychelles: The relevant legislation is made up of the Patents Act, Chapter 156 (1991) and the Trade Marks Decree, Chapter 239 (1991). Following the implementation of the country's Intellectual Property Development Plan, the country has enacted the Industrial Property Act, 2014 (Act No. 7 of 2014), which is TRIPS-compliant and came into force on 1 March 2015.⁴¹

South Africa: South Africa has numerous pieces of relevant legislation, which include the Patents Act, the Trade Marks Act 1993, the Designs Act 1993, the Plant Breeders Rights Act 15 of 1976 and the Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008. The 2013 report noted that "the South African intellectual property rights system is arguably the most advanced in the region and the legislation is on a par with international trends and in line with all requirements" (United Nations, 2015, p. 30). As noted above, since 2013, South Africa has been considering amendments to its intellectual property laws and a draft intellectual property policy has been prepared. The country's laws do not fully maximize TRIPS flexibilities, and many of the changes suggested in the intellectual property policy pertain to patents and health.

Zimbabwe: The following acts regulate industrial property: Patents Act (Chapter 26:03), Trade Marks Act (Chapter 26:08), Geographical Indications Act (Chapter 26:06), Integrated Circuit Layout Design Act (Chapter 26:07), Intellectual Property Tribunal Act (Chapter 26:01), Plant Breeders Rights Act (Chapter 18:16) and Merchandise Marks Act (Chapter 14:13). Most of this legislation is post-TRIPS and has been found to be TRIPS-compliant.

In the case of developing countries, a wide array of legislation providing for industrial property exists, and TRIPS compliance also varies widely.

Legislation on copyright and related rights

a. Least developed countries

Angola: In general, copyright is regulated by Law No. 4/90 of 10 March 1990 on Author's Rights. The Decree on Videograms and Phonograms (2005) provides specific regulation in relation to videograms and phonograms.

Democratic Republic of the Congo: Copyright is regulated by Ordinance-Law No. 86-033 of 5 April 1986 on the Protection of Copyright and Neighbouring Rights, which includes the protection of traditional cultural expressions.

⁴⁰ Namibia, Industrial Property Act, 2012 (Act No. 1 of 2012). Government Gazette, No. 4907 (23 March 2012).

⁴¹ Industrial Property Act (Commencement) Notice, 2014 SI 109/2014, 12/22/2014.

Lesotho: Copyright is regulated by the Copyright Order No. 13 of 1989, which extends protection to traditional cultural expressions. This law has been found to be in compliance with the Berne Convention, but not with the TRIPS Agreement (United Nations, 2015, p. 25).

Madagascar: Copyright is regulated by Law No. 94-036 of 1995 on Literary and Artistic Property; Decree No. 98-435 of 1998 on General Rules for the Collection of Copyright and Neighbouring Rights; Decree No. 90-260 of 1990, modifying the provisions of Decree No. 84-389 of 1984, establishing the Malagasy Copyright Office; and Decree No. 84-390 of 1984, on Regulation of Copyright Royalties. Madagascar is a party to the Berne Convention on the Protection of Literary and Artistic Works and the Beijing Treaty on Audiovisual Performances, but not to the later WIPO Copyright Treaty. The country's copyright laws are outdated (United Nations, 2015, p. 26).

Malawi: Copyright is regulated by the Copyright Act of 1989, Chapter 49:03, and the Copyright (Production, Importation and Distribution of Sound and Audio Visual Recordings) Licensing Regulations, 2007. The country's Copyright Act predates TRIPS and is thus non-compliant. Given that Malawi is a least developed country, such compliance is not yet required.

Mozambique: Copyright is regulated by the Law on Copyright and Related Rights - Law No. 42/01 of 27 February 2001; the Regulation on the Compulsory Affixing of Seals to Phonograms - Decree No. 27/2001 of 11 September 2001; and the Regulation on Implementation and Feasibility Rules in Decree No. 27/2001 of 11 September 2001 and Ministerial Order No. 8/2003 of 15 January 2003. These laws, like the industrial property laws, are TRIPS-compliant.

United Republic of Tanzania: On mainland Tanganyika, copyright is regulated by the Copyright and Neighbouring Rights Act No. 7 of 1999, the Copyright and Neighbouring Rights (Production and Distribution of Sound and Audiovisual Recordings) Regulations, 2006, and the Copyright and Neighbouring Rights (Registration of Members and their Works) Regulations, 2005. On Zanzibar, copyright is regulated by the Zanzibar Copyright Act No. 14 of 2003. Both sets of copyright legislation were promulgated after TRIPS and are TRIPS-compliant. In 2014, WIPO reported that it was providing technical assistance to Zanzibar in relation to the review of its copyright law.⁴²

Zambia: Copyright is regulated by the Copyright and Performance Act (Chapter 406) and the Competition and Fair Trading Act (Chapter 417). As noted above, the 2013 study found that Zambia's "national laws are generally not adequate in protecting IP rights".

All the least developed countries have copyright legislation, but it is, in general, not yet TRIPS-compliant.

⁴² World Intellectual Property Organization, Technical Assistance Database: Activity Details. Available from www.wipo.int/tad/en/activitydetails.jsp?id=6788.

b. Developing countries

Botswana: Copyright is regulated by the Copyright and Neighbouring Rights Act, 2000 (Act No. 8 of 2000)⁴³ CAP 68:02 (2005 Amendment Act: entry into force 1 October 2006).

Eswatini: Copyright (Prohibited Importation) Act No. 35 of 1918 and Copyright Act No. 36 of 1912. In 2010, it was reported that Cabinet had approved the Copyright and Neighbouring Rights Bill of 2010 (Schultz, 2010), but it is not clear whether it has come into effect.

Mauritius: Copyright is regulated by the Copyright Act 2014 (entry into force 31 July 2014), which also includes the protection of traditional cultural expressions. This law is TRIPS-compliant.

Namibia: Copyright is regulated by the Namibian Copyright and Neighbouring Rights Protection Act (Act 6 of 1994). According to the 2013 study, this Act was amended in 2001 and is undergoing further review (United Nations, 2015, p. 29).

Seychelles: Copyright is regulated by the Copyright Act, 2014 (Act No. 5 of 2014), which came into force on 1 August 2014 and repealed the Copyright Act, Chapter 51 (1991). This law was developed pursuant to the intellectual property development plan and is TRIPS-compliant.

South Africa: Copyright is regulated by the Copyright Act 1978, the Copyright Regulations 1978, the Registration of Copyright in Cinematograph Films Act No. 62 of 1977 and the Registration of Copyright in Cinematograph Films Regulations 1980. Although the Copyright Act is technically TRIPS-compliant (United Nations, 2015, p. 30), it does not cater adequately for certain public interest needs. For example, its exceptions and limitations have been found to be too narrow to promote access to learning materials (Schonwetter, Ncube and Chetty, 2010, pp. 231-280).

Zimbabwe: Copyright and Neighbouring Rights Act, Industrial Design Act (Chapter 26:02) (Act 11/2000, 22/2001 (s. 4), 32/2004).⁴⁴ This law is TRIPS-compliant.

All the SADC member States in the developing country category have copyright legislation, the majority of which is TRIPS-compliant.

Trade-Related Aspects of Intellectual Property Rights compliance

Table 7 presents a summary of the TRIPS compliance position of SADC member States, with comments on the status of each one. For those developing countries that are not yet compliant, urgent steps need to be taken to ensure compliance.

⁴³ It is noted in the WIPO Intellectual Property Laws and Treaties Database that this law retains the title and year of the earlier version, even though it was adopted in 2006. According to article 1, "This Act may be cited as the Copyright and Neighbouring Rights Act, 2000". See www.wipo.int/wipolex/en/details.jsp?id=9583 (accessed 7 January 2015).

⁴⁴ Zimbabwe, Copyright and Neighbouring Rights Act, Chap. 26:05, available from www.unesco.org/culture/pdf/anti-piracy/Zimbabwe/zb_copyright_2000_en.

Table 7: Trade-Related Aspects of Intellectual Property Rights (TRIPS) compliance among Southern African Development Community member States

Country	Status	Comments on TRIPS compliance
Angola	Least developed	
Botswana	Developing	Post-TRIPS legislation which complies with TRIPS minimum standards
Democratic Republic of the Congo	Least developed	
Eswatini	Developing	The most recent WTO trade policy review of Eswatini in 2009 found that the intellectual property framework was not yet fully TRIPS-compliant ^a
Lesotho	Least developed	
Madagascar	Least developed	
Malawi	Least developed	
Mauritius	Developing	TRIPS-compliant, with a very recent Copyright Act that includes traditional cultural expressions
Mozambique	Least developed	TRIPS-compliant
Namibia	Developing	Industrial property laws are TRIPS-compliant, and the copyright legislation is undergoing review to ensure compliance
Seychelles	Developing	Became a member of the World Trade Organization in April 2015
South Africa	Developing	South Africa's intellectual property legislation is TRIPS-compliant ^b
United Republic of Tanzania	Least developed	TRIPS-compliant
Zambia	Least developed	
Zimbabwe	Developing	The most recent WTO trade policy review of Zimbabwe in 2011 found that the intellectual property framework is TRIPS-compliant ^c

^a World Trade Organization (2009a), p. 422.

^b For commentary, see Maister and van Woensel (2013).

^c World Trade Organization (2011).

As observed earlier, least developed countries are not yet required to be TRIPS-compliant. While their legislation is currently outdated, there is therefore no urgent requirement for amendment. What is more urgent is for the SADC member States classified as developing countries to ensure that their legislation is compliant. The major shortcoming is in relation to the use of TRIPS flexibilities, which will be discussed in chapter 4, where the pertinent recommendations will be outlined.

D. Administration infrastructure on intellectual property

This section presents an outline of the intellectual property administration arrangements in member States, in the form of a list of the government offices that administer intellectual property through the registration of rights. Most countries will have an office that registers industrial property rights and not a copyright office, as copyright subsists automatically, and registration is not constitutive. Some countries have a government office or other agency that serves as a copyright office. Where this is the case, it will be noted. Table 8 indicates whether the relevant country is party to the Patent Cooperation Treaty or the African Regional Intellectual Property Organization Harare Protocol, given that these are key mechanisms, indicating either participation or non-participation.

Angola: The Angolan Institute of Industrial Property (Ministry of Geology, Mines and Industry) serves as the Industrial Property Office and administers intellectual property rights for trademarks, patents and designs. Substantive examination of patents has not been performed (Adams and Adams, 2012, p. 42). The National Institute for Cultural Industries (National Directorate of Entertainment and Copyright, Ministry of Culture) serves as the copyright office. Angola is a party to the Patent Cooperation Treaty system but not to the African Regional Intellectual Property Organization's patent cooperation system, given that Angola is not a member State of it.

Democratic Republic of the Congo: The Secretariat General of Culture (Directorate of Research, Planning and International Cultural Relations, Ministry of Culture and the Arts) serves as the copyright office. The Directorate of Industrial Property

Table 8: Participation in the Patent Cooperation Treaty and the Harare Protocol

Country	Patent Cooperation Treaty	Harare Protocol
Angola		X
Botswana		
Democratic Republic of the Congo	X	X
Eswatini		
Lesotho		
Madagascar		X
Malawi		
Mauritius	X	X
Mozambique		
Namibia		
Seychelles		X
South Africa		X
United Republic of Tanzania		
Zambia		
Zimbabwe		

(Secretariat for Industry and Small and Medium Enterprises at the Ministry of Industry and Small and Medium-Sized Enterprises) serves as the industrial property office. It has been noted that this office is “poorly developed and ... limited to registration of a few foreign intellectual property titles” (United Nations, 2015, p. 28). Substantive examination of patents is not performed and patents are subjected only to scrutiny of whether they comply with formal requirements (Adams and Adams, 2012, p. 121). The Democratic Republic of the Congo does not subscribe to the terms of the Patent Cooperation Treaty or the African Regional Intellectual Property Organization Harare Protocol patent application systems.

Eswatini: Industrial property is administered by the Intellectual Property Office, Ministry of Commerce, Industry and Trade. It also has oversight of copyright. Eswatini is a party to both the Patent Cooperation Treaty and the African Regional Intellectual Property Organization’s patent cooperation systems.

Lesotho: The Registrar General’s Office (Ministry of Law and Constitutional Affairs) serves as the industrial property and copyright office. In general, patent applications are subjected only to a formal examination, followed by a substantive examination that is undertaken by the African Regional Intellectual Property Organization under the Harare Protocol (Adams and Adams, 2012, p. 248). Lesotho also participates in the Patent Cooperation Treaty system. The 2013 study notes that “there is [an] urgent need to streamline the Patent Office so that it can only deal with the core functions of an IP office”, and “to create a semi-autonomous institution” (United Nations, 2015, p. 25). As mentioned above, an interministerial committee is driving the proposed national intellectual property plan for Lesotho. This committee is also competent to coordinate intellectual property cooperation among the various relevant ministries.

Madagascar: Administration is carried out by the Malagasy Industrial Property Office in the case of industrial property, and the Malagasy Copyright Office. Substantive examination is not carried out because the office has no qualified examiners (United Nations, 2015, p. 26). Madagascar participates in the Patent Cooperation Treaty system, but is not a party to the Harare Protocol, given that Madagascar is not an African Regional Intellectual Property Organization member State. Madagascar was previously a member State of the Organisation africaine de la propriété intellectuelle, but withdrew.

Malawi: Administration of industrial property rights is handled by the Registrar of Patents, while the Copyright Society of Malawi undertakes copyright administration. Patent applications may be submitted through the African Regional Intellectual Property Organization under the Harare Protocol or through the Patent Cooperation Treaty system.

Mozambique: The administration of industrial property is undertaken by the Mozambique Institute of Intellectual Property. Copyright falls under the Department of Copyright in the Ministry of Culture, Youth and Sports. It is possible to file patent applications under both the Patent Cooperation Treaty and African Regional Intellectual Property Organization systems. The 2013 study noted that “the linkage [of] the intellectual property office [with] industries is being carried out through the

Patent Promotion Units. However, [the] lack of expertise has delayed this project" (United Nations, 2015, p. 32).

United Republic of Tanzania: Industrial property administration is undertaken by the Business Registrations and Licensing Agency for the mainland, while the Zanzibar Business and Property Registration Agency serves Zanzibar. The United Republic of Tanzania is a party to both the Patent Cooperation Treaty and African Regional Intellectual Property Organization's patent cooperation systems. The Copyright Society of Zanzibar at the Ministry of Constitutional Affairs and Good Governance serves as the copyright office for Zanzibar, while the Copyright Society of Tanzania does the same for the mainland.

Zambia: Administration is by the Patents and Companies Registration Agency, which is an executive agency of the Ministry of Commerce, Trade and Industry. Zambia is a party to both the Patent Cooperation Treaty and African Regional Intellectual Property Organization's patent cooperation systems. The Ministry of Information and Broadcasting Services deals with copyrights and neighbouring rights.

All the least developed countries have administrative structures in place; however, they are often fragmented and poorly resourced.

Botswana: The Office of the Registrar of Companies and Intellectual Property (Ministry of Trade and Industry) administers both industrial property and copyright. Botswana is a party to both the Patent Cooperation Treaty and the African Regional Intellectual Property Organization Protocol and participates in both patent cooperation systems. Substantive examination of patent applications is undertaken by the African Regional Intellectual Property Organization on behalf of Botswana (Adams and Adams, 2012, p. 62). A Technical Committee on Intellectual Property Rights is in place to coordinate intellectual property approaches (United Nations, 2015, p. 27), but information pertaining to its membership and detailed mandate and an account of its activities to date are not publicly available. The Companies and Intellectual Property Authority Act, 2011 (Act No. 14 of 2011) has been enacted but has not yet come into force. When it does so, it will establish an authority that will appoint the following functionaries:⁴⁵

- a) Registrar of companies and business names, who shall be the head of the companies and business names office;
- b) Registrar of industrial property, who shall be the head of the industrial property office;
- c) Copyright administrator, who shall be the head of the copyright office.

Mauritius: The Controller of Industrial Property Office heads the Industrial Property Office, which is part of the Ministry of Foreign Affairs, Regional Integration and International Trade. Patent applications are subjected to formal examination (Adams and Adams, 2012, p. 327). Mauritius does not participate in the Patent Cooperation

⁴⁵ Companies and Intellectual Property Authority Act, 2011 (Act No. 14 of 2011), section 25 (1).

Treaty or the African Regional Intellectual Property Organization/Harare Protocol patent application system. The Mauritius Society of Authors (Ministry of Arts and Culture) has oversight of copyright matters. It has been reported that an intellectual property council would be set up to coordinate and lead national intellectual property initiatives.⁴⁶ This is an important and significant move that should facilitate coherence on intellectual property matters.

Namibia: As observed by the 2013 study, the Ministry of Information and Communication Technology is the custodian of the Copyright Act, while the Directorate for Audiovisual Media and Copyright Services deals with day-to-day activities relating to copyright issues (United Nations, 2015, p. 29). The Ministry of Trade and Industry has been the custodian of the industrial property office. It is possible to file patent applications under both the Patent Cooperation Treaty and the African Regional Intellectual Property Organization systems. The country has established a business and intellectual property authority to administer industrial property rights.⁴⁷

Seychelles: Patents and trademarks fall under the administration of the Office of the Registrar General. The Copyright Act falls under the purview of the Department of Culture. Seychelles is not an African Regional Intellectual Property Organization member.

South Africa: Industrial property is administered by the Companies and Intellectual Property Commission (Department of Trade and Industry). South Africa participates in the Patent Cooperation Treaty system but is not a party to the African Regional Intellectual Property Organization's Harare Protocol because it is not a member of it.

Zimbabwe: The Zimbabwe Intellectual Property Office has oversight over both industrial property and copyright. Zimbabwe is a party to both the Patent Cooperation Treaty and the African Regional Intellectual Property Organization patent cooperation systems. The country established an interministerial committee on intellectual property in 2013 to coordinate the efforts of relevant ministries.

As is the case with least developed countries, the administrative infrastructure in the developing countries is, in general, fragmented. Nevertheless, efforts are being made in a number of countries to coordinate the infrastructure through structures such as interministerial committees or intellectual property councils. The administrative infrastructure in developing countries is also better resourced than that in least developed countries.

⁴⁶ World Trade Organization, "Chairs programme supports intellectual property workshop in Mauritius". Available from www.wto.org/english/news_e/news14_e/chair_05mar14_e.htm (accessed 8 January 2015).

⁴⁷ See www.bipa.gov.na/.

E. Assessment of the level of harmonization of policies, legislation and intellectual property rights infrastructure

As has been shown above, many SADC member States are currently involved in policy formulation. Many policies, however, are currently in draft form or not yet publicly available for comparison in order to determine levels of harmonization. Harmonization allows for a general level of commonality with respect to matters of principle, such as an appropriate stance on an approach to the negotiation of international agreements. It does allow for countries to deal with specificities at national level, where aspects that are peculiar are captured in the national policies guided by the overall regional framework. In this regard, the African group at WIPO, to which SADC member States belong, has articulated a very clear pro-developmental intellectual property approach from which SADC could consolidate and apply the principles. In addition, the Principles for Intellectual Property Provisions in Bilateral and Regional Agreements developed at the Max Planck Institute for Intellectual Property and Competition Law could be applied in SADC.

Basic harmonization is illustrated by the extent to which the intellectual property legislation of some of the member States classed as “developing countries” is TRIPS-compliant. The same cannot be said, however, with regard to the member States classed as least developed countries. As integration deepens, it is desirable for the policies to be harmonized for reasons advanced in chapter 1. In addition, as stated in chapter 2, the laws of SADC member States have to conform to binding international standards, be compliant with agreed regional approaches, ensure substantive fairness, effectiveness and efficiency and be simple, clear and accessible.

There are two prominent practices in relation to the administration infrastructure for intellectual property rights. One is to have a separate office or body to administer industrial property and another to administer copyright. The second is to have one office with oversight of both industrial property and copyright. Given that copyright administration is minimal, because there is no mandatory registration, either practice is acceptable. Some countries (e.g., Botswana and Lesotho) have outsourced their substantive patent examination to the African Regional Intellectual Property Organization. However, given that not all SADC members are members of it, some countries do not have the benefit of this shared resource. Accordingly, it was recommended in the 2013 study that such States should strongly consider joining the African Regional Intellectual Property Organization in order to benefit from this resource.

Furthermore, in relation to intellectual property administration, the establishment of semi-autonomous, appropriately staffed and resourced intellectual property offices was recommended in the 2013 report.

F. Summary

The intellectual property landscape has been reviewed in this chapter with regard to policy, legislation and administration infrastructure in the SADC region through

a country-by-country analysis. Differences were observed in intellectual property policies within the region and there were calls for the progressive elements in these policies to be incorporated into the regional framework and guidelines. The guidelines will then be used to craft policies for those countries without policies. The region can also take advantage of support from WIPO in the crafting of the regional framework. WIPO has developed a national policy toolkit, and this could be used by the region. Allusion was made to various intellectual property administration systems in the region and emphasis placed on the importance of coordination in the administration of intellectual property issues. Examples of such a coordinated structure are an interministerial committee or an intellectual property council. This will ensure that the country applies a uniform and consistent approach to intellectual property matters. It was also observed that not all SADC member States are members of the Patent Cooperation Treaty or the African Regional Intellectual Property Organization, and they were therefore encouraged to consider membership so as to benefit from the shared resources and efficiencies offered.

Chapter 4: Crafting a regional cooperation framework on intellectual property rights that optimally exploits the flexibilities of the Trade-Related Aspects of Intellectual Property Rights Agreement

A. Introduction

There are at least three approaches that can be used by regional economic communities when they endeavour to align national legal frameworks: cooperation, harmonization and unification (for a fuller discussion, see Ncube, 2015). Cooperation means merely sharing resources in specific areas but does not require that all policies, laws or processes be the same. It is a prudent starting point because no immediate changes are required at this stage and States may simply begin to work together and share resources, where possible. An example of the successful use of this approach is by the Association of Southeast Asian Nations (ASEAN) community using its 1995 Framework Agreement on Intellectual Property Cooperation. The details of such cooperation are given below. Harmonization entails that States agree on specific basic or minimum legal standards, but leaves policy space or scope for the parties to modulate their national frameworks in a way that suits national aspirations. Harmonization respects variable geometry. This is the model used for the global intellectual property framework and for the African Regional Intellectual Property Organization framework. Unification is when the laws are exactly the same and States cede sovereignty and have no scope to modulate the framework domestically. This is the model used by the Organisation africaine de la propriété intellectuelle.

This chapter features a discussion of the key considerations that have to be borne in mind in the creation of a harmonized framework for intellectual property rights that meaningfully makes use of flexibilities provided in the TRIPS Agreement. Its focus is on patent-related flexibilities because these are of immediate relevance to the current work of SADC on its pharmaceutical business plan. The chapter proceeds by providing an overview of patent-related flexibilities, followed by a summary of SADC work performed in relation to its pharmaceutical business plan, and a discussion of how other regional economic communities approach the incorporation of flexibilities into their frameworks.

B. Flexibilities

“The term ‘TRIPS flexibilities’ refers to those provisions in the TRIPS Agreement that provide some policy space for party States to calibrate their domestic intellectual property regimes”, argues Ncube (2016a, p. 14).⁴⁸ Flexibility is mentioned in the preamble of the Agreement, which provides that the parties to the Agreement entered

⁴⁸ For discussion of the development of the phrase, see Blakeney and Mengistie (2011), pp. 243-244 and 238-264. See also World Intellectual Property Organization (2010a).

into it recognizing “the special needs of the least developed country members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base”.

A concrete manifestation of the recognition of the need for such flexibility for least developed countries is found in article 66, which provides the following:

In view of the special needs and requirements of least developed country members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such members shall not be required to apply the provisions of this agreement, other than articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of article 65. The Council for TRIPS shall, upon duly motivated request by a least developed country member, accord extensions of this period.

The transition period for TRIPS compliance referred to above is an important flexibility extended to least developed countries. It affords least developed countries some time to aspire to their socioeconomic development goals, including the establishment of the technical and structural capacity necessary before they are obliged to ensure that their intellectual property regimes are TRIPS-compliant. As mentioned above, this period was recently extended to 2021. This means that least developed countries have, to date, been given 26 years (1995 to 2021) to become fully compliant with TRIPS.⁴⁹ In some instances, some least developed countries, for example member States of the Organisation africaine de la propriété intellectuelle, have adopted TRIPS standards before the expiry of the transition periods, a move that has been characterized as premature and ill-advised (Deere, 2008, p. 1) on the grounds that their national socioeconomic conditions were not yet suitable for TRIPS and the full transition period would have been better spent improving physical infrastructure and other aspects of their economies. Indeed, it is difficult to say that the early adoption of TRIPS standards has resulted in increased economic development for these States, all of whom have failed to progress from “least developed country” status since the adoption of these standards in 1997. Accordingly, a key recommendation of the present study is that member States of SADC classified as least developed countries should not hasten their adoption of TRIPS standards before the expiry of the transition period or before they progress from their current status.

There are various ways of classifying TRIPS flexibilities (Ncube, 2016a, p. 16), which include:

- a) Whether they relate to transition periods or substantive issues (World Intellectual Property Organization, 2010a, para. 35);
- b) Intellectual property right with which the flexibilities are associated;

⁴⁹ For commentary on the value of these transitional periods for least developed countries, see Nkomo (2015).

- c) Purpose or goal being sought by the State (Correa, 2014);
- d) Timing of the availability of the flexibility.

The first classification entails simply distinguishing whether the flexibility relates to a substantive matter or has to do only with a transition period that is extended to a party before it is obliged to comply with substantive provisions. The second classification allows one to categorize flexibilities depending on the type of intellectual property to which they apply, for example, as a copyright-related flexibility or a patent-related flexibility. The third categorization refers to the reason why a State may resort to a specific flexibility. For example, it may do so to meet public health goals by making pharmaceuticals more readily available at lower prices or to curb anti-competitive activities. Table 9 depicts available patent-related flexibilities according to their purpose.

With regard to the timing of the availability of the flexibilities, States may resort to them in the process of the acquisition of the right, in defining the scope of the right and in the process of enforcing the right (World Intellectual Property Organization, 2010a, para. 36).

In this instance, the question being asked is, “At what stage in the life cycle of the intellectual property right is the flexibility relevant?” This relevance could be at the time of creation or the time of acquisition. At these stages, what matters is how the invention is depicted in formal or substantive terms when the patent application is made. For example, it could be about the disclosure requirements that dictate how much information an applicant must provide in the application (World Intellectual

Table 9: Patent-related flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods

Purpose	Flexibility	Relevant Trade-Related Aspects of Intellectual Property Rights provision
To prevent the appropriation of subject matter existing in nature	Definition of “invention”	Article 27.1
To avoid patents on minor developments or undue limitations to legitimate competition	Determination of level of patentability requirements	Article 27.1
To ensure access to products at lower prices	Parallel imports; compulsory licences	Article 6, article 31
To remedy anti-competitive practices	Compulsory licences	Article 31 (k)
To permit the local exploitation of patented inventions	Compulsory licences	Article 31
To allow follow-on innovation	Research exception	Article 30
To speed up competition after patent expiry	“Bolar exception”	Article 30

Source: Correa (2014), pp. 417-418, table 14.1.

Property Organization, 2010a, para. 37). When it comes to the scope of rights flexibilities, the concern is about what is covered by intellectual property protection and how the public interest is used as a basis for permitting uses of the invention. Examples of this include compulsory licences and provisions pertaining to parallel imports (World Intellectual Property Organization, 2010a, para. 38). Regarding enforcement, the key concern is the national provision for remedies for infringement, such as punitive damages in instances of wilful or flagrant infringement (World Intellectual Property Organization, 2010a, para. 39).

A single flexibility can fall into more than one of these categories, and so compulsory licences are rightly described as “patent-related flexibilities that serve public health goals and are available post-patent grant” (Ncube, 2016a, p. 16). There are flexibilities that are relevant to all forms of intellectual property rights, but a full discussion of these is beyond the scope of the current study. The following section discusses patent-related flexibilities.

C. Patent-related flexibilities

Definition of “invention” and other flexibilities related to patent grants

Article 27, paragraph 1 of the TRIPS Agreement provides for the following:

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of article 65, paragraph 8 of article 70 and paragraph 3 of this article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

The definition of what counts as an “invention” affords TRIPS party States some flexibility, which they can use in various ways, including prohibiting “evergreening” or the obtaining of further patents on additional uses of already patented pharmaceuticals (Musungu, Villanueva and Blasetti, 2004, p. 15). An example of such a practice is when, a few years before the expiry of patent over a pharmaceutical compound, the patent holder changes its pharmaceutical composition slightly and seeks a patent over the new composition. Alternatively, a new use could be found for the original composition (second medical indication), and a new patent is registered. It has been recommended that national legislation should exclude new uses of compounds from patentability (Ibid.). Other aspects covered by flexibilities that member States could address include the patentability criteria of inventive steps, required disclosure and whether there is substantive patent examination (Correa, 2014, and Sibanda, 2013).

Use of patentability criteria flexibilities by Southern African Development Community member States

Pharmaceutical patents are granted by all SADC member States, although the least developed country member States could have benefited from the transition period

afforded them for granting these patents until January 2016. Only Malawi, Namibia and Zambia prohibit the patenting of new uses of pharmaceutical compounds.

Parallel imports

The concept of parallel importation entails purchasing goods that are lawfully available in a market (x) and importing them into another (y) where they are then traded without the authorization of the relevant intellectual property rights holder, in competition with the intellectual property rights holder or the holder's licensees (Ncube, 2016a, p. 18; Musungu, Villanueva and Blasetti, 2004, p. 13). The principle of exhaustion of rights determines whether parallel importation is lawful in a jurisdiction. The essence of this principle is that the intellectual property rights holder's rights are exhausted or fall away after the first sale of the goods in question. Once the rights are exhausted, by virtue of the purchase in market x, then the intellectual property rights holder has no cause for complaint against the trade of the goods in market y. There are two variations of this principle, namely, national and international exhaustion. Under the principle of national exhaustion, the rights are exhausted when the product is first distributed on the national market. In contrast, under international exhaustion, its distribution anywhere in the world exhausts the patent holder's rights. In countries that apply national exhaustion, it is not possible to parallel import lawfully. Parallel importation enables access to products from another market when they are not available or are unaffordable in a person's country of residence, and has been used in various contexts, including the purchase of generic medication for HIV/AIDS.⁵⁰

The TRIPS provision that grants policy space to parties to provide for parallel importation in their national laws is article 6, under which, "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."⁵¹

Each member State of WTO is at liberty to select which regime of exhaustion applies. Where international exhaustion applies, a citizen or resident of that country is then able to purchase the product from another market and import it into their country of residence.

Parallel importation in the Southern African Development Community

Ten SADC member States do not have an international exhaustion regime, so parallel importation is not possible. Three have national exhaustion regimes, namely, Madagascar, Mozambique and the United Republic of Tanzania (Musungu, 2012, p. 10; Musungu, 2010), while the rest have no provisions on exhaustion at all. Five member States have an international exhaustion regime, namely, Botswana, Mauritius, Namibia, South Africa and Zimbabwe (Ibid.). South Africa has enacted provisions to

⁵⁰ For example, see Heywood (2001) for an account of how activists brought HIV/AIDS medication into South Africa.

⁵¹ Also see para. 5(d) of the Doha Declaration on the TRIPS Agreement and Public Health, WTO document WT/MIN(01)/DEC/2. Available from www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

enable the parallel import of medication in section 15C of its Medicines and Related Substances Control Act, which provides for the following:

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may:

- a) Notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
- b) Prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the Council in the prescribed manner, may be imported;
- c) Prescribe the registration procedure for, [and] the use of, the medicine referred to in paragraph (b).

The relevant regulations are the General Regulations, Medicines and Related Substances Regulations.⁵² These provisions were contested when they were introduced, leading to a court application to halt them, which was ultimately withdrawn.⁵³

Compulsory licences and government use

Another way of facilitating the manufacture of and access to generic medication⁵⁴ is the use of compulsory licences. These licences are “granted by an administrative or judicial body to a third party to exploit an invention without the authorization of the patent holder” (Musungu, Villanueva and Blasetti, 2004, p. 12). Article 31 of the TRIPS Agreement sets out a series of conditions under which they may be issued, including the provision that satisfactory remuneration must be paid to the patent holder, with due consideration to the “economic value of the [licence]” (article 31(h)), and that the medicines manufactured under compulsory licence shall be “predominantly for the supply of the domestic market” (article 31(f)). This limitation stops countries with the requisite capacity for manufacturing generic medicines from exporting a significant amount of those generic medicines to countries that do not have such a capacity (usually developing or least developed countries) (Ncube, 2016a, p. 19). This limitation has since been modified by the “paragraph 6 solution” of the 2003 Waiver

⁵² South Africa, Government Gazette 24727, GNR510 of 10 April 2003 (date of commencement 2 May 2003).

⁵³ For an account of the case and the arguments made therein, and the developments leading to its withdrawal, see Heywood (2001).

⁵⁴ Generics are medicines that consist of “the same active medicinal substance as an originator pharmaceutical product. Because it acts in the same way in the human body, it is interchangeable with the originator product” according to Ncube (2009), pp. 680-1.

Decision, which is currently a pending amendment to TRIPS.⁵⁵ This modification has removed the limits on exports under compulsory licence to the member States of WTO that have limited pharmaceutical product manufacturing capacity, provided that the relevant member States comply with stated conditions (Ncube, 2016a, p. 19). It requires that both the exporting and importing countries issue compulsory licences and advise the TRIPS Council of the import and export. It has only been used once, however, by Rwanda and Canada (For commentary, see Ncube (2016a), pp. 686–87; Andemariam (2007); Reichman and Abbott (2007); Outtersson (2010), p. 673; Nkomo (2013a)), owing to its complexity and cumbersome nature.

Compulsory licences in Southern African Development Community member States

It is one thing to have legislative provision for compulsory licences and another actually to implement the provisions and issue compulsory licences. All SADC member States have provisions for compulsory licences in their laws (Musungu, 2012, p. 10; Musungu, 2010), but in reality only a few of them, such as Zambia and Zimbabwe, have issued compulsory licences (Sibanda, 2013). This limited use of compulsory licences underscores the point “that there are many practical and capacity problems that attach to the local manufacture of generics” (Ncube, 2016a, p. 25. For examples, see Owoeye, 2014, and United Nations Conference on Trade and Development, 2011). A detailed discussion of these, however, is beyond the scope of this study, which focuses on the regulatory framework.

It has been noted that, as of September 2012, none of the SADC member States had domesticated the 2003 waiver. The waiver has now been incorporated into TRIPS by the amendment, which came into force on 23 January 2017 (World Trade Organization, 2017).

In view of the above, it is recommended that SADC member States:

- a) Issue compulsory licences under their current legislative frameworks. It is necessary to stimulate local or regional generic manufacturing capacity so that the means to implement the licences are available;
- b) Domesticate the TRIPS waiver provision (article 31bis) so that they can re-export generics and benefit from pooled procurement.

Exceptions

Article 30 of the TRIPS Agreement stipulates that “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not

⁵⁵ Article 31bis of the 2005 Protocol amending the TRIPS Agreement. The amendment will come into force after its acceptance by two thirds of World Trade Organization members, and in the interim the waiver decision applies. For a list of World Trade Organization members accepting the amendment of the TRIPS Agreement, see www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed 30 August 2017). See also WTO General Council decision of 26 November 2013, Amendment of the TRIPS Agreement – Fourth extension of the period for the acceptance by members of the Protocol amending the TRIPS Agreement, document WT/L/899.

unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

The above provision sets out three criteria that exceptions must meet (the so-called Three-Step Test). Examples of permissible exceptions under this provision include those for research and experimentation, and for early working, which is also known as the “Bolar provision” (Musungu, Villanueva and Blasetti, 2004, p. 17). Inventors and manufacturers have scope under the research and experimentation exception to use patented technology (e.g., a product or pharmaceutical) in an experimental manner in order to create alternatives.⁵⁶ Bolar provisions enable competitors to use or otherwise exploit patented pharmaceuticals to make a generic version, then to obtain “the regulatory approval and registration of a generic product before the expiry of the patent term” (ibid.).

Southern African Development Community member States’ use of exceptions

Legislation in Eswatini and Madagascar appears to include the research and experimentation exception, but the relevant provisions are vague and do not cover commercially driven research (Ncube, 2016a, p. 26; Musungu, 2012, p. 10; Musungu, 2010). By contrast, Botswana, the Democratic Republic of the Congo, Lesotho, Mauritius, Mozambique, Namibia and the United Republic of Tanzania have specific exemption provisions for research that unequivocally cater for this exception (ibid.). The rest of the SADC member States have no provisions that cover research exemptions (Ncube, 2016a, p. 26). Only Botswana, Namibia, South Africa and Zimbabwe have early working (Bolar) exemptions (ibid.).⁵⁷ SADC member States that have not already done so ought to enact specific research exemption and early working (Bolar) provisions.

Box 3 contains a summary of current work being undertaken in SADC member States on patent-related flexibilities under the SADC pharmaceutical business plan during the period 2007–2013 in order to make full use of TRIPS flexibilities.

⁵⁶ Musungu, Villanueva and Blasetti (2004); World Trade Organization, Canada – Patent Protection of Pharmaceutical Products: Report of the Panel. Document WT/DS114/R. Available from www.wto.org/english/tratop_e/dispu_e/7428d.pdf.

⁵⁷ See also Ncube (2009), p. 685, for an outline of South Africa’s Bolar exemption provision.

Box 3: Southern African Development Community (SADC) Southern Africa Regional Programme on Access to Medicines and Diagnostics: work on patent-related flexibilities

SADC has a pharmaceutical business plan the emphasis of which is on the use of the TRIPS flexibilities as a strategy to make good-quality medicines more affordable to citizens in member States. The Trade, TRIPS and Access to Medicines project is being run with the Southern Africa Regional Programme on Access to Medicines and Diagnostics, supported by funding from the United Kingdom of Great Britain and Northern Ireland's Department for International Development and UK Aid. The project has a Technical Working Group. To date, it has undertaken a number of activities that include national stakeholder meetings (e.g., in Zimbabwe in January 2014 and Lesotho in August 2014); the preparation of briefing papers ("Trade, TRIPS and access to medicines: challenges and options for the SADC region", 2012) and reports ("Pharmaceutical patents, TRIPS flexibilities and access to medicines in Southern African Development Community (SADC)", (2012)).

The key recommendations to SADC member States include the following:

- Domestication of article 31bis of the TRIPS Agreement to create a larger market for the regional pharmaceutical manufacturing industry
- Finalization of intellectual property policies to inform legislative reform
- Review of legislation and policies that are relevant to intellectual property to ensure "that they are in line with international intellectual property obligations, incorporate TRIPS flexibilities and give effect to national developmental aspirations".

Information obtained from www.sarpam.net/sarpam-newsletter-march-may-2014# and www.sarpam.net/reports.

D. East African Community and Common Market for Eastern and Southern Africa approaches to implementing flexibilities

It is instructive to look to other regional economic communities to see how they coordinate their TRIPS flexibility options. The following sections will briefly look at the East African Community and COMESA.

As mentioned in chapter 2, the East African Community has a policy on TRIPS flexibilities that includes 11 policy statements (see table 10).

Table 10: East African Community's approach to implementing TRIPS flexibilities

1.	<ul style="list-style-type: none"> a. All East African Community partner States that are least developed countries are to take advantage of the 2016 transition period and provide in their national patent laws for an extension of this period, as may be agreed upon by the Council for TRIPS. b. All East African Community partner States are to abolish any "mailbox" provision in their existing or draft national patent laws.
2.	<p>East African Community partner States are to strictly define in the patent laws and/or patent examination guidelines the patentability criteria, and apply them strictly in order to keep a broad public domain. In particular, they shall:</p> <ul style="list-style-type: none"> a. Strictly apply the novelty standard through considering a wide concept of prior art consisting of everything disclosed to the public whether by use, in written or oral form, including patent applications, information implied in any publication or derivable from a combination of publications, which are published anywhere in the world and to which the general public can actually or theoretically have access. b. Clearly define the inventive step standard by referring to a "highly" skilled person. c. Strictly apply the industrial application requirement and limit the patentability of research tools to only those for which a specific use has been identified.
3	<ul style="list-style-type: none"> a. East African Community partner States are to exclude from patentability: <ul style="list-style-type: none"> i. Natural substances including microorganisms, even if purified or otherwise isolated from nature. ii. New medical uses of known substances, including microorganisms: East African Community partner States seeking to consider new medical uses principally patentable as processes under the patentability criteria shall strictly apply the patentability requirements on a case-by-case basis. iii. Derivatives of medical products that do not show significantly enhanced therapeutic efficacy/significant superior properties. b. East African Community partner States, in order to protect small-scale innovations (e.g., in the areas of traditional medicines or genetic resources), shall reward such inventors with a right to compensation from third parties who use the inventions for follow-on improvements (use-and-pay/compensatory liability).
4	<p>In order to increase legal certainty with regard to the scope of research [exceptions], East African Community partner States shall amend their patent provisions on research exceptions as follows:</p> <ul style="list-style-type: none"> a. Explicitly authorize research for scientific, non-commercial and commercial purposes. The preponderant purpose of commercial research must be the generation of new knowledge of the patented substance. b. Provide a right to claim a non-exclusive licence for the use of patented research tools against payment of compensation.
5	<p>In order to allow early market entry for generic producers, East African Community partner States shall amend their national patent law provisions on marketing approval/"Bolar" exception to:</p> <ul style="list-style-type: none"> a. Authorize the use of patented substances by interested parties for marketing approvals by national and foreign medicines regulatory authorities. b. Clarify the scope of the marketing approval/"Bolar" exception to the effect that generic producers may use patented substances for acts "reasonably related" to the development and submission of information required for marketing approvals.

6	<ul style="list-style-type: none"> a. East African Community partner States (least developed country partner States only upon the lapse of the 2016 (or future) transition period for least developed countries) should adopt a system to protect test and other data against unfair commercial use and disclosure, while leaving the local medicines regulatory authorities free to rely on the results of original test data from domestic or foreign approvals when assessing the safety and efficacy of generic competing products (misappropriation approach). b. None of the East African Community partner States may establish a linkage between patent protection and marketing authorization that would prevent medicines regulatory authorities from granting marketing approval for generic medicines before the lapse of the relevant patent.
7	<p>East African Community partner States shall require patent applicants:</p> <ul style="list-style-type: none"> a. To disclose all modes and expressly indicate the best mode for carrying out an invention by experts skilled in the art, who reside in the relevant East African Community partner State. b. To disclose the International Non-proprietary Name of a pharmaceutical substance or an active pharmaceutical ingredient as soon as it is available.
8	<ul style="list-style-type: none"> a. East African Community partner States, in addition to post-grant tribunal/court procedures, are to provide in their national patent laws for effective pre-grant and post-grant administrative patent opposition procedures. b. East African Community partner States that are also African Regional Intellectual Property Organization members are to discuss an amendment to the Harare Protocol as follows: <ul style="list-style-type: none"> i. To take account of third-party opposition. ii. To subject patents in their territories that were granted by the African Regional Intellectual Property Organization to the written approval of the relevant national patent offices, which shall be submitted to the African Regional Intellectual Property Organization within a reasonable period of time beyond the current six months.
9	<p>East African Community partner States shall admit international intellectual property rights exhaustion under the following laws:</p> <ul style="list-style-type: none"> i. Patent law. ii. Copyright law. iii. Trademarks law.

10	East African Community partner States shall:	
	a.	Be free to determine and stipulate in their national patent laws the grounds upon which compulsory licences may be granted.
	b.	Amend the compulsory licensing provisions in patent laws to include a provision authorizing the export of up to 100 per cent of pharmaceutical production to countries lacking sufficient pharmaceutical capacities.
	c.	Draft guidelines and regulations both as exporting and importing countries on the export/importation of pharmaceutical products into countries with insufficient pharmaceutical manufacturing capacities under draft article 31bis, TRIPS Agreement/paragraph 6 decision.
	d.	When importing pharmaceutical products under the draft article 31bis, TRIPS Agreement/paragraph 6 decision, waive remuneration for import compulsory licences where its value has been taken into account when remunerating the patent right holder in the exporting country.
	e.	Include in their patent laws a provision stating that the remuneration shall not exceed the United Nations Development Programme-recommended figure of 4 per cent, and take anti-competitive behaviour into account when determining the amount of remuneration.
	f.	Include in their patent laws a maximum period of 90 days for prior negotiations.
	g.	Spell out in their patent laws all four situations in which prior negotiations can be waived, namely, in [cases] of national emergency, other situations of extreme urgency, public non-commercial use/government use, and to remedy anti-competitive behaviour of the patent right-holder.
	h.	Exclude injunctive relief as a remedy available under independent review of government use licences.
	i.	Authorize administrative entities to grant all kinds of compulsory licences.
11	To prevent anti-competitive behaviour and abuses of patent rights by their owners and to support technology transfer, East African Community partner States shall:	
	a.	List, borrowing from Kenya, Rwanda, United Republic of Tanzania-Mainland or Uganda patent laws, licensing terms that may be considered unjustified restrictions of competition, and authorize the patent registrar to refuse the registration of such licensing contracts.
	b.	Provide for remedies to patent right abuse, such as compulsory licences.

Source: East African Community (2013), pp. 12-21.

This is a commendable approach, which SADC is encouraged to emulate because it provides clear guidelines to member States and ensures a harmonized approach. In addition, it is of great assistance to member States that lack the legal technical expertise to craft the laws and policies necessary, given that it presents them with a thoroughly researched set of proposals and so eliminates the need for them to spend financial resources on procuring the proposals necessary from elsewhere.

COMESA has no policy on TRIPS flexibilities similar to that of the East African Community. Analysis of member States' intellectual property frameworks has shown that many of the COMESA member States have domesticated some of the TRIPS flexibilities, with the unfortunate failure to domesticate the waiver decision that would enable the export of pharmaceuticals (Cardno Emerging Markets and Enabling Environments Ltd., 2011, p. 3). Recommendations to the COMESA member States are similar to those made above for consideration by SADC. For example, COMESA member States have been urged to accept the 2005 TRIPS Amendment and to domesticate its provisions (ibid., p. 6). Other recommendations that have been made in relation to COMESA member States' national intellectual property frameworks are listed in table 11.

Table 11: Common Market for Eastern and Southern Africa (COMESA) recommendations on TRIPS flexibilities

a.	Develop COMESA guidelines on time limits for prior attempts to negotiate voluntary licences with patent-holders (excluding cases in which no prior attempt is required) and on royalty rates for compulsory licensing, including a zero rate in which remuneration has been paid under compulsory licence in the exporting country, and other procedural conditions.
b.	Urge COMESA member States that have not already done so to implement international exhaustion of patents, including through legislation if necessary, to allow parallel imports.
c.	Urge COMESA member States that have not already done so to implement the marketing approval exception to allow use of a patent for purposes of obtaining pharmaceutical registration prior to the expiry of the patent to hasten generic competition.
d.	Urge COMESA member States with significant pharmaceutical-manufacturing capacity to remove any legal barrier to their use of the regional trade mechanism as exporting countries. Specifically, patent law provisions that production under compulsory licence shall be primarily to supply the domestic market should be amended to allow unlimited export to other COMESA member States that share the health problem in question.
e.	Consider amendment of the COMESA competition regulations to allow the COMESA Competition Commission to make orders derogating from the direct enjoyment of the privileges and protection conferred by patent laws in cases of abuse of dominant position by patent holders in the regional market.
f.	Recommend that least developed country member States exercise the flexibility granted to them by the World Trade Organization (WTO) not to make available patent protection for pharmaceutical products until the end of the transitional period for least developed countries under the TRIPS Agreement and any extensions that may be granted.
g.	Request the WTO TRIPS Council to grant a further extension of the transitional period for least developed countries so that they will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2021.
h.	Urge those COMESA member States that have not already done so to deposit instruments of acceptance of the Protocol Amending the TRIPS Agreement to place the importation mechanism and regional trade mechanism on a permanent basis.

Source: Adapted from Cardno Emerging Markets and Enabling Environments Ltd (2011), pp. 23-24.

E. Summary

This chapter has presented the key considerations regarding TRIPS flexibilities and placed an emphasis on the need for countries to utilize the benefits offered within the flexibilities. The review has shown that the intellectual property challenges of the three regional economic communities (East African Community, COMESA and SADC) are similar. SADC can learn from the experience of the East African Community and COMESA, its partners in the Tripartite Agenda. For example, the East African Community approach of having a regional protocol and policy is commendable, given that it provides extra support to member States. SADC could consider a similar approach. Similarly, the regional intellectual property guidelines developed by COMESA could provide SADC with a starting point in harmonization.

Chapter 5: Summary of findings, conclusions and recommendations

A. Introduction

The objectives of this study are to develop a regional intellectual property rights framework for SADC member States that is harmonized and complies with international rules and standards. The regional framework includes templates for policies (template 1) and for legislation and infrastructure relating to intellectual property rights (template 2). In addition, the harmonized regional framework is required to be supported by a common approach to international cooperation by SADC member States. This chapter brings together the findings in chapters 1 to 4 and uses them as a basis for the framework that is presented here.

The first major point to be made is that any changes to be considered, suggested and implemented must be aligned with the public interest goals of member States and must be appropriate for their level of economic development. Member States of SADC classed as “least developed countries” should not therefore hasten their adoption of standards on trade-related intellectual property rights before the expiry of the transition period or before they progress from their current least developed status. Similarly, they should take full advantage of all flexibilities afforded to them by virtue of their least developed status.

Second, any harmonization efforts should take cognizance of existing regional cooperation approaches on intellectual property, such as that undertaken through the African Regional Intellectual Property Organization and the annex on intellectual property rights to the agreement on a Tripartite Free Trade Area. Nevertheless, policymakers should appreciate that, because SADC member States have differing levels of participation in these forums, they have different obligations to meet. For example, not all SADC member States are African Regional Intellectual Property Organization members, and so they are not obliged to domesticate the African Regional Intellectual Property Organization framework. This study has benchmarked their legislation against TRIPS standards, by which they are all bound (subject to the compliance extension granted to least developed countries). In view of the benefits to be derived from cooperation through the African Regional Intellectual Property Organization, which includes access to substantive examination of patents, it is recommended that those SADC member States that are not African Regional Intellectual Property Organization member States should consider joining it. In this way, they will benefit from a framework that is more suited to their regional socioeconomic conditions and, at the same time, is TRIPS-compliant.

In crafting a regional framework for SADC, it is important to look at best practice and adapt accordingly. The review of the content and structure of the South African intellectual property framework provided in chapter 2 demonstrated that the framework is sound and could inform the regional approach. The South African framework is “domestic” to some extent, given that the country shares

similar socioeconomic conditions to the rest of SADC. The adaptation of the South African system should take into account concerns about the protection of traditional knowledge, the delay in finalizing an intellectual property policy and the country's approach to intellectual property in publicly funded research. Careful consideration is needed in the adaptation of the South African system.

In addition, chapter 2 provided a consideration of the experience of three regional economic communities and intergovernmental organizations, namely, the East African Community, COMESA and the Southern African Customs Union, in intellectual property harmonization. This is particularly important because intellectual property harmonization efforts within SADC must be aligned with the COMESA-East African Community-SADC intellectual property agenda, the aspirations for the continental free trade area and the ultimate goal of establishing an African economic community. The East African Community has taken a much more robust approach to maximizing the use of TRIPS flexibilities through a protocol and policy, and SADC should consider using this approach. Protocols are the primary and most effective way in which SADC member States can give legal effect to standards agreed throughout the Community, and therefore protocols could underpin any decisions on intellectual property rights (article 22 of the SADC Treaty).

The state of SADC member States' national intellectual property frameworks presented in chapter 3 considered policy, legislation, TRIPS compliance and intellectual property administration. It was found that the majority of member States are already crafting intellectual property policies with technical assistance from WIPO. It is not immediately apparent, however, whether these policies have the same focus, given that not all of them were available for scrutiny. A regional policy guidance framework for intellectual property is needed to inform these efforts and to ensure a harmonized regional approach, and this guideline will serve as a tool for States to review their existing policies. In any event, as a member of the COMESA-East African Community-SADC Tripartite Free Trade Area, SADC has regional policy guidance on intellectual property in the form of the annex to the Free Trade Area Agreement on intellectual property. It is suggested that existing policies should be reviewed against this annex, and that policies that are being developed should be aligned to it.

It is further suggested that the SADC secretariat can assist member States by collecting and reviewing the intellectual property policies that are already in place in some SADC member States in order to extract the key beneficial elements. This can inform the policies of those countries that do not yet have policies. WIPO has invested significant resources in preparing a national policy toolkit and providing technical assistance to developing countries busy with formulating their policies. It is also currently assisting numerous member States in the formulation of their national policies on intellectual property. It is recommended that countries that do not yet have intellectual property policies and are not yet working with WIPO on policies should tap into this expertise and assistance.

In relation to legislation, as noted above, least developed countries are not yet required to comply with the TRIPS Agreement. Although their legislation is currently outdated, it does not need to be amended urgently. What is more urgent is for the SADC member States classed as developing countries to ensure that their legislation

is compliant. The major shortcoming is in relation to the use of TRIPS flexibilities, which was discussed in chapter 4. The pertinent recommendations are outlined below.

With regard to administration of intellectual property, SADC member States have taken different approaches to developing national infrastructure on intellectual property. In countries that do not have a single administration agency for intellectual property and have several ministries involved in intellectual property matters, it is suggested that care be taken to coordinate the agencies and ministries through an appropriate structure. One example of such a structure is an interministerial committee, as has been established in Zimbabwe, and is also proposed by the 2016 South African Intellectual Property Consultative Framework; and the Intellectual Property Council to be established in Mauritius, which is intended “to bring together all the various institutions dealing with IP for a more coherent and coordinated approach, and provide guidance in the design and implementation of intellectual property policies” (World Trade Organization, 2014a). It is acknowledged that setting up such structures could face challenges if cooperation among various ministries cannot be guaranteed.

Chapter 4 highlighted the mixed use of flexibilities by SADC member States and noted that full use of flexibilities had not yet been achieved throughout the region. In particular, no member State has domesticated the waiver decision (article 31bis of the TRIPS Agreement) that would form the basis of bulk imports into one country and re-export into the rest of the region. The following specific recommendations were made about flexibilities:

- a. SADC member States are encouraged to issue compulsory licences under their current legislative frameworks. It is necessary to stimulate local or regional generic manufacturing capacity so that the means are available to implement the compulsory licences;
- b. In addition, they are encouraged to domesticate the waiver provision (article 31bis of the TRIPS Agreement) so that they can re-export generics and benefit from pooled procurement;
- c. SADC member States ought to enact specific provisions for exemptions for research and early working (Bolar exception);
- d. SADC ought to consider formulating a protocol and policy on TRIPS flexibilities, together with guidelines for the domestication of the flexibilities for member States.

In addition to the above, Blakeney and Mengistie (2011, p. 251) recommend the use of regional cooperation configurations such as SADC and the African Regional Intellectual Property Organization to lead their member States in the following activities:

- a. Awareness-raising on the role of intellectual property rights in innovation and industrial development;

- b. Identification of best government practices and incentives to support research and development leading to intellectual property rights;
- c. Assistance to universities and research institutions in developing intellectual property policies and support services;
- d. Outreach and awareness-raising about the commercial application of intellectual property rights.

The following section presents a framework and action plan through which these recommendations could be driven by the SADC secretariat.

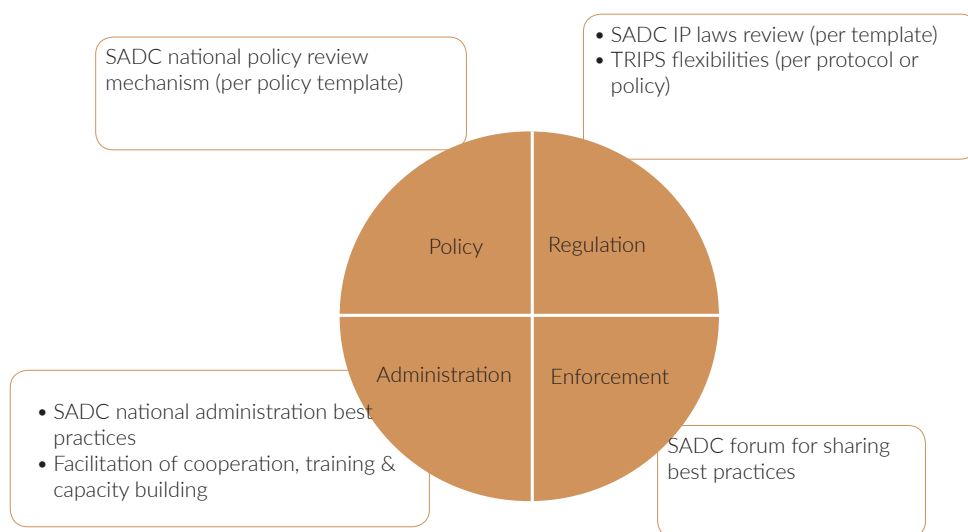
B. Proposed Southern African Development Community cooperation framework for intellectual property rights

The components of the suggested SADC regional framework are illustrated in figure 2.

The main elements of a sound framework for intellectual property rights and an overview of recommended SADC interventions are policy (including an express statement on the regional approach to international intellectual property law-making); regulatory instruments; administration structures; and enforcement mechanisms.

As stated earlier, policy provides clarity and guidance to various government departments that currently deal with intellectual property and those that will do so in the future. It is important that this policy be articulated in writing. In this context, SADC should provide guidance on the structure and content of sound policy on intellectual property that is harmonized throughout the community.

Figure II: Components of the Southern African Development Community (SADC) regulatory framework



Regulatory instruments, such as acts and regulations, make policies justiciable. As shown in chapter 2, legislation in some SADC member States is outdated. As observed in chapter 4, patent laws fail to make full use of relevant TRIPS flexibilities. In this regard, it has been recommended that SADC should prepare a regional protocol and policy to assist member States in incorporating these flexibilities.

Intellectual property laws create rights primarily through registration, with the exception of copyright, which subsists automatically. Therefore, the structures necessary for the registration and maintenance of these rights are required. Chapter 3 showed that SADC member States used varying approaches to administrative structures and that they did not have independent intellectual property offices that were properly equipped, funded and staffed. In this context, SADC could offer a platform through which best administrative practices and resources for personnel development and training could be shared.

Once rights are created, avenues for recourse in the case of infringement or disputes are necessary. It was observed in the 2013 study (United Nations, 2015) that enforcement is ineffective in some SADC member States. SADC can offer a platform for sharing best practices and resources for training enforcement and judicial officers.

The substantive content of the above elements has been the subject of previous chapters, and this section focuses only on the means to apply it. The ASEAN community⁵⁸ has developed a sound regional intellectual property framework that will be used as the basis of the suggestions made here.⁵⁹ ASEAN is a good comparator because, as with SADC, its membership consists of developing States that are members of WTO and are bound by the TRIPS Agreement. As with SADC, it is also working towards continental economic integration through the ASEAN Economic Community that was established on 31 December 2015.

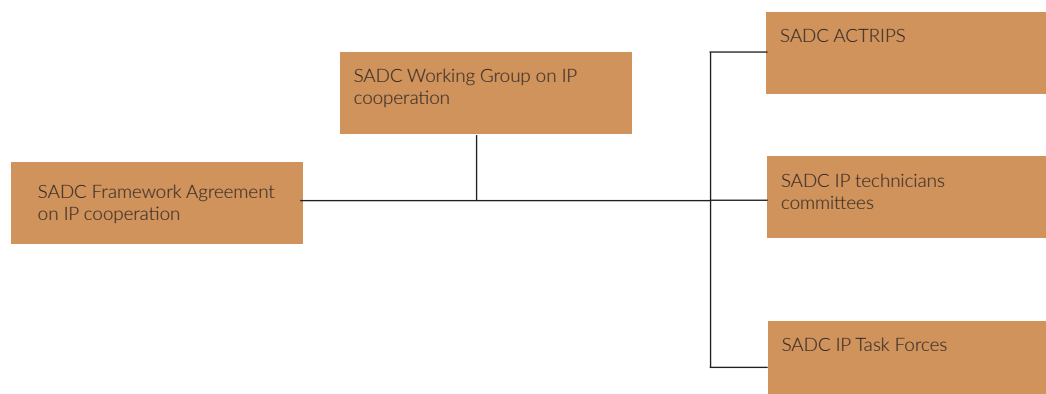
The ASEAN regional framework for intellectual property is grounded in its Framework Agreement on Intellectual Property Cooperation of 1995. The development of the Framework has been driven by a working group on intellectual property cooperation, which was formed in 1996. This cooperation was initially intended to be in the shape of full harmonization, to be achieved by 2020. The details of implementation were detailed in the ASEAN intellectual property rights action plan and the workplan for ASEAN cooperation on copyrights, 2004-2010. According to Ncube (2016a):

“This plan was updated when it was realized that full harmonization was not practicable due to the varying degrees of economic development among member States. It was realized that a more reasonable approach would be to seek cooperation in a way that allowed member States to meet their diverse national goals whilst at the same time pursuing regional interests and imperatives. In addition, the programme was accelerated by five years and a new plan known as the ASEAN Intellectual Property Rights Action Plan 2011-2015 was developed”.

58 The member States are Brunei Darussalam, Cambodia, Indonesia, the Lao People's Democratic Republic, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Viet Nam.

59 For a full discussion of this framework and how it was developed, see Siew-Kuan Ng (2013).

Figure III: Suggested Southern African Development Community (SADC) cooperation infrastructure on intellectual property



It is suggested that the region should proceed in a manner similar to ASEAN and seek to cooperate on intellectual property through a regional framework that is set out in an action plan and driven by a working group (see figure 3). Such a working group might consist of ministers responsible for intellectual property matters or their representatives. The group would serve as a high-level interministerial forum. In addition, it is recommended that task forces and technical committees should be set up to consider specific aspects. This approach has also been used by ASEAN, which has a task force on AIDS (Association of Southeast Asian Nations Task Force on AIDS and ASEAN secretariat, 2005). The establishment of an advisory council on trade-related innovation policies would be a valuable means of coordinating “training, research, information exchange and political coordination in the use of TRIPS flexibilities for public health promotion and protection” (Musungu, Villanueva and Blasetti, 2004, pp. xiv-xv). The council could have oversight of SADC’s cooperation with the African Regional Intellectual Property Organization and other intellectual property organizations. Its membership would be at an appropriate level of government official to ensure continuity.

The regulatory framework necessary would be developed under the guidance of this structure. For example, it might be necessary to formulate protocols and policy to implement the various recommendations summarized above. Templates 1 and 2 are offered as a point of departure to this end. It is important to note that the substantive contents of a national intellectual property policy cannot be authored without following a due process that involves national consultation and the setting of priorities. The template accordingly offers only a broad structure for the elements that ought to be included in the policy. The elements of the templates are presented below.

C. Overview of Template 1

Template 1 (see annex I) contains a proposal that the structure of a national intellectual property policy ought to contain the following elements:

- a) An overview of the country's socioeconomic profile that includes its development goals. This is necessary to ground or contextualize the policy. An indication of the primary trade areas, natural resources, employment patterns and key activities in the informal sector will make it immediately apparent which types of intellectual property a country should be focusing on;
- b) Findings of an intellectual property audit. These need to be included to provide an overview of the current state of intellectual property law in the country and to highlight any priority areas. Such an audit must include technology transfer, technology licensing and FDI to enable full analysis of the existing framework;
- c) The country's vision, mission and objectives can be set out, on the basis of the above two sections and on a national consultative process that has enabled stakeholders to present their concerns and requests;
- d) The national development agenda. Any development plans and relevant international, subregional and continental obligations have to be factored into the vision, mission and objectives;
- e) In the light of the above, it will then be possible to engage with the main policy issues. These would typically include:
 - i. Health: patents and access to medicines, full use of TRIPS flexibilities, promotion of technology transfer and development of local research;
 - ii. Education: copyright and access to knowledge, issues relevant to cultural industries;
 - iii. Agriculture: genetic resources and plant breeders' rights;
 - iv. Traditional knowledge: protection;
 - v. Competition: intersection with intellectual property law;
 - vi. Intellectual property and publicly funded research;
 - vii. National institutional capacity;
 - viii. National enforcement;
 - ix. Public education and awareness campaigns, including targeted training and capacity-building on intellectual property for specific industries, for example, the development of intellectual property training programmes for health sector and technical staff;

- x. (Regional and international cooperation approach to international intellectual property law-making.

Once the above policy matters have been canvassed, it is necessary to make provision for policy implementation through a project-based approach, with specific activities, actions, resources and champions.

Given that national conditions are dynamic, it is necessary to provide for periodic review of the policy. It is also necessary to put in place monitoring and evaluation procedures so that policy implementation progress can be tracked and necessary adjustments can be made.

D. Road map for domestication of the policy template on intellectual property

A road map for the domestication of the intellectual property policy template is presented in annex II. It is in the form of a Gantt chart that depicts a framework for scheduling the different activities.

E. Overview of Template 2

Template 2 (see annex III) presents a suggested national legal and regulatory framework and infrastructure for intellectual property. It is comprised of three parts. Part 1 lists the following key elements of a national legislative framework on intellectual property:

- a) Industrial property;
- b) Copyright and related rights;
- c) Plant breeders' rights;
- d) Traditional knowledge and genetic resources.

The template highlights the following main issues that should, in general, be considered in relation to all legislation:

- a) Compliance with TRIPS and relevant regional and subregional obligations and standards;
- b) Making use of TRIPS flexibilities;
- c) Coherence with related national laws, such as consumer law and competition law.

The second part of template 2 lists the following national institutions that are required to administer intellectual property:

- a) Industrial property registry;
- b) Copyright and related rights administration (e.g., a copyright board);
- c) Plant breeders' rights registry;
- d) Traditional knowledge and genetic resources administration and database, such as South Africa's National Indigenous Knowledge Systems Office and National Recordal System.

Some of these agencies may be located in various ministries, as is the case with South Africa, where the industrial office registry is located in the Department of Trade and Industry, and the National Indigenous Knowledge Systems Office and National Recordal System are under the Department of Science and Technology. The location of agencies in various ministries is understandable owing to the cross-cutting nature of intellectual property. Departments may take different approaches to intellectual property, and this can be addressed through an interministerial coordination unit that facilitates cross-departmental discussions and the standardization of approaches. In addition, a written national policy on intellectual property would go a long way in informing departmental approaches and harmonizing them.

Part 2 highlights the main issues to consider in relation to administrative infrastructure:

- a) Capacity for substantive patent examination;
- b) Opportunities for regional, continental or international cooperation;
- c) Automation;
- d) Coordination of various national agencies or consolidation into one agency;
- e) Interministerial coordination.

Part 3 of the template focuses on enforcement. It lists the following core elements of a national enforcement structure and strategy for intellectual property: court infrastructure and capacity for both civil remedies and criminal sanctions, and border control mechanisms.

As noted above, these structures have to be equipped and resourced adequately with both the physical infrastructure and human resources necessary to enable them to function. In relation to human resources, investment needs to be made in training both enforcement and judicial officers in the relevant laws and their application.

F. Road map for improving the legal, regulatory and administrative framework

This template is accompanied by a project-based road map (see annex IV) for its implementation. The projects will be organized under programmes, which will be identified through an intellectual property audit involving stakeholder participation. Examples of appropriate programmes include the formulation of a national policy on intellectual property, updating the legal and regulatory landscape and achieving efficiency in the infrastructure for working on intellectual property.

An action plan has to be developed for each project. These action plans must encompass the tasks required to accomplish the programme goals, an indication of the persons or entities responsible for those tasks and a timeline by which the tasks have to be completed. The annex presents two action plans as models of what an action plan should consist of.

G. Conclusion

In summary, the current study presents the following recommendations:

- a) SADC member States must benchmark their legislation against TRIPS, subject to the caveat that least developed countries must take advantage of the compliance extension granted to them. SADC member States classed as developing countries must ensure that their legislation is compliant;
- b) SADC member States that are not yet members of the African Regional Intellectual Property Organization ought to consider joining the organization so that they may benefit from a framework that is more suited to their regional socioeconomic conditions than other available international frameworks and is also TRIPS-compliant;
- c) SADC member States may consult the South African intellectual property framework as a model to emulate, but they must not indiscriminately adopt it. At the very least, care needs to be taken in relation to the problematic aspects highlighted in the report;
- d) SADC member States that do not have a single administration agency for intellectual property but have several ministries involved in intellectual property matters ought to coordinate the agencies and ministries through an appropriate structure, such as an interministerial committee or an intellectual property council;
- e) SADC member States that are not working with the Patent Cooperation Treaty or the African Regional Intellectual Property Organization are also encouraged to consider joining them in order to benefit from the shared resources and efficiencies that they offer;

- f) SADC's intellectual property harmonization efforts must be aligned with the COMESA-East African Community-SADC intellectual property agenda and the ultimate goal of establishing a continental free trade area and an African economic community. To this end, SADC ought to formulate a protocol and policy on TRIPS flexibilities, together with guidelines for the domestication of the flexibilities for member States;
- g) SADC member States ought to create regional national policy guidelines on intellectual property that are aligned with the annex on intellectual property to the Tripartite Free Trade Area Agreement. These guidelines will then be used to review existing national policies on intellectual property and to inform the formulation of policies for countries that do not have policies;
- h) SADC member States also ought to continue making use of the WIPO national policy toolkit and technical assistance as they formulate policy;

To make full use of available flexibilities related to patents, SADC member States ought to:

- i. Legislate an international exhaustion regime;
- ii. Issue compulsory licences under their current legislative frameworks. It is necessary to stimulate local or regional generic manufacturing capacity so that the means to implement the licences are available;
- iii. Domesticating the waiver provision so that they can re-export generics and benefit from pooled procurement;
- iv. Enact specific research exemption and early working (Bolar) provisions (if they have not done so already).

Table 12 provides a summary of the key findings and recommendations.

Annex I

Table 12: Key findings and recommendations for Southern African Development Community (SADC) intervention

Key findings	Recommendations		
	Member State	SADC	SADC tool/template
Intellectual property legislation: outdated laws	Conduct an intellectual property audit; benchmark legislation against TRIPS; fully utilize flexibilities, including transition periods for least developed countries; emulate strong national frameworks *African Regional Intellectual Property Organization member States must domesticate the African Regional Intellectual Property Organization framework	Provide guidance on legislation and the incorporation of flexibilities to encourage regional harmonization	Template 2 and road map for legislative drafting or amendments Protocol on patent-related TRIPS flexibilities
Intellectual property policy: lacking in some States; some variations in SADC member States	Formulate national policy on intellectual property	Provide guidance on national intellectual property policies to encourage regional harmonization	National policy guidelines on intellectual property for formulation or review Template 1 and road map
Intellectual property administration: fragmented and uncoordinated in certain States; lacks autonomy; suffers from resource and personnel constraints	Coordinate agencies and ministries through an appropriate structure, such as an interministerial committee or an intellectual property council Consider joining the Patent Cooperation Treaty and African Regional Intellectual Property Organization so as to benefit from the shared resources and efficiencies they offer	Provide guidance on administrative infrastructure, including training, and provide a forum for sharing best practices	
Intellectual property enforcement: poorly resourced	Empower enforcement agencies	Provide guidance and training	

Annex II

Template 1 - National policy on intellectual property

Introduction and background

Country profile

Overview of intellectual property

Vision, mission and objectives

Link the intellectual property strategy to the national development agenda, national visions, national development plans, regional and continental aspirations

Analysis of existing framework

To include technology transfer, technology licensing and foreign direct investment

Main policy issues

Health: patents and access to medicines; full use of TRIPS flexibilities; promotion of technology transfer and development of local research

Education: copyright and access to knowledge, copyright and cultural industries

Agriculture: genetic resources, plant breeders' rights

Traditional knowledge: protection

Competition: intersection with intellectual property law

Intellectual property and publicly funded research

National institutional capacity

National enforcement

Public education and awareness campaigns, including targeted training and capacity-building on intellectual property for specific industries, for example, the development of intellectual property training programmes for health sector and technical staff

Regional and international cooperation

Approach to international law-making on intellectual property

Implementation plan for policy on intellectual property

Project-based with specific activities, actions, resources and champions

Impact assessment and periodic policy review

Monitoring and evaluation framework

Road map for domestication of the policy template on intellectual property

Activity	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1. Approve the development of a national intellectual property policy								
2. Designate the coordinating office								
3. Appoint national team								
4. Appoint international consultant								
5. Train project team on the overall process								
6. Carry out desk research								
7. Conduct interviews with stakeholders (data collection)								
8. National consultations to validate the audit findings								
9. Prepare final audit report								
10. Develop first draft national policy on intellectual property								
11. National consultations to validate the first draft national policy on intellectual property								
12. Prepare second draft national policy on intellectual property								
13. Present draft to a stakeholders' forum								
14. Prepare final draft based on feedback obtained during national consultations								
15. Prepare final policy document								
16. Submit to government for adoption								
17. Launch policy								

Source: World Intellectual Property Organization. Methodology for the Development of National Intellectual Property Strategies. Tool 1: The Process (2016). Available from www.wipo.int/edocs/pubdocs/en/wipo_pub_958_1.pdf.

Annex III

Template 2: National legal and regulatory framework and intellectual property infrastructure

Key elements of a national intellectual property framework

- a. Industrial property
- b. Copyright and related rights
- c. Plant breeders' rights
- d. Traditional knowledge and genetic resources

Main issues to consider

Compliance with TRIPS; use of TRIPS flexibilities; coherence with related national laws, for example, consumer law and competition law.

Institutions managing IP

- a. Industrial property
- b. Copyright and related rights
- c. Plant breeders' rights
- d. Traditional knowledge and genetic resources

Main issues to consider:

Capacity for substantive patent examination; opportunities for regional, continental or international cooperation; automation; coordination of various national agencies or consolidation into one agency; interministerial coordination.

Enforcement

Court infrastructure and capacity for both civil remedies and criminal sanction
Border control mechanisms

Annex IV

Road map for improving the legal, regulatory and administrative framework

The road map will be project-based. The projects will be organized under programmes. These programmes will be identified through an intellectual property audit that involves stakeholder participation. Examples of appropriate programmes include:

Formulation of a national intellectual property policy

Updating the legal and regulatory landscape

Achieving efficiency in the intellectual property infrastructure

An action plan has to be developed for each project. An example of two project action plans follows.

Project 2.1: Streamline and eliminate gaps in industrial property laws

Programme	Tasks	Responsibility/potential partners	Timeline
2	<p>Revising and merging the various industrial property laws that currently exist (Patent Registration Act, Trademarks Act and any other relevant statutes)</p> <p>Including in the Act provisions on protection of genetic resources, geographical indications, promotion and protection of technological innovations, integrated circuits and topography and industrial designs</p> <p>Including provisions that incorporate TRIPS flexibilities</p>	<p>Registrar(s) of industrial property</p> <p>Southern African Development Community advisory council on trade-related innovation policies</p> <p>World Intellectual Property Organization</p> <p>African Regional Intellectual Property Organization</p> <p>World Trade Organization</p>	

Project 3.1: Rationalize and strengthen administration institutions on intellectual property

3	<p>Conduct a study of intellectual property administration institutions</p> <p>Identify capacity gaps in:</p> <p>Efficiency and service delivery</p> <p>Coordination between agencies</p> <p>“Soft” infrastructure (human resources, corporate tools)</p> <p>Physical infrastructure</p> <p>Equipment</p> <p>Design measures to develop capacities in the identified gaps</p>	<p>Registrar(s) of industrial property</p> <p>Copyright office</p> <p>Tertiary education and training institutions</p> <p>SADC advisory council on trade-related innovation policies</p> <p>World Intellectual Property Organization</p> <p>African Regional Intellectual Property Organization</p> <p>Business sector</p>	
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