BREAKING IP BARRIERS
Creating Pathways to Medicine Access

Advocacy Toolkit for Civil Society:

Intellectual Property & Access to Medicines in Mozambique

ARASA
AIDS & Rights Alliance for Southern Africa

SAPAM
HEALTH SYSTEMS STRENGTHENING

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About ARASA

The AIDS and Rights Alliance for southern Africa (ARASA) was established in 2002 as a regional partnership of civil society organisations working in 18 countries in Southern and East Africa. Between 2019 and 2021, the partnership will work to promote respect for and the protection of the rights to bodily autonomy and integrity for all in order to reduce inequality, especially gender inequality and promote health, dignity and wellbeing in southern and east Africa.

ARASA conducts its work in a multi-dimensional, multi-level and multi-directional operational approach under two programme areas, namely (i) capacity strengthening; and (ii) advocacy, both of which utilise the diversity of the ARASA partnership to build and strengthen the capacity of civil society for advocacy and have regional and national components. ARASA also works to elevate the experiences of our partners to influence international health policy and to advise global political, health and financing institutions.

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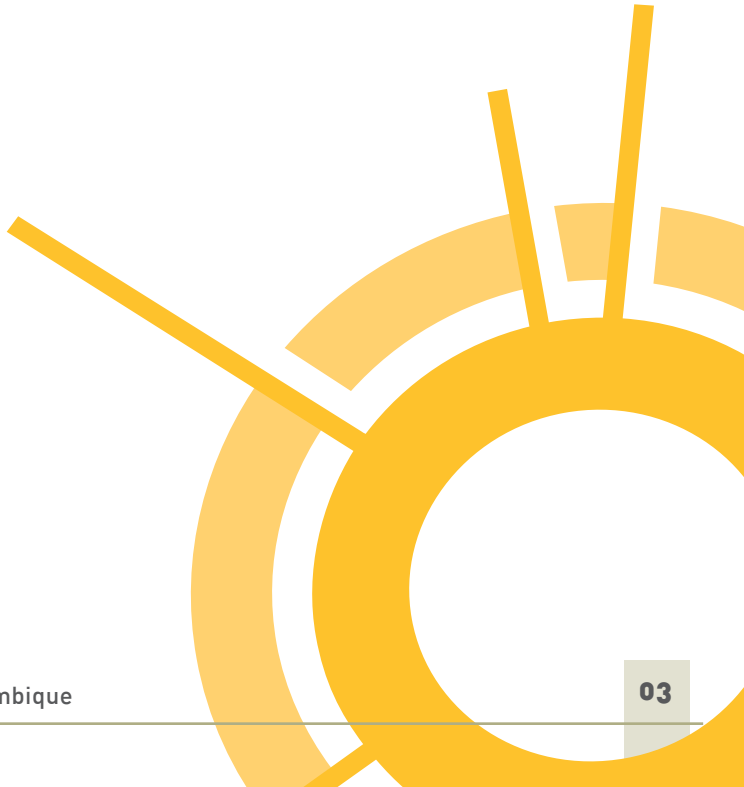

1. INTRODUCTION

Many reports document that intellectual property (IP) rights have had significant impact on global access to medicines and treatment. The situation is no different in Mozambique where intellectual property law has an increasing role in defining rights of IP right holders and determining how medicines are developed and accessed. [1]

The world faces an increasing need to ensure access to essential medicines to all. IP rights may be a barrier to ensure such increased access to safe essential medicines. It is within this context that States, and particularly the least developed countries (LDCs) are called to use flexibilities provided for in protection of IP to ensure that everyone, in their jurisdictions, has access to essential medicines and treatment.

In exercising its role as watchdog of State actions civil society (CSO) also have a role in ensuring increase in access to safe and essential medicines and treatment. Most CSOs are not equipped with a full understanding of IP regulations and the opportunities available for them to play a meaningful role on expanding access to treatment. This Toolkit aims to close that gap and provide CSOs in Mozambique the information required for them to advocate to increase access to medicines.

This Toolkit comprises three main sections:

1. The first section provides and introduction to Mozambique normative and regulatory framework on intellectual property and access to medicines aiming to equip civil society with understanding of the basics normative and regulatory framework on intellectual property and access to medicines in Mozambique.

2. The second part identifies potential areas for civil society engagement with institutions tasked with intellectual property and access to medicines.

3. The third part lists crucial contacts and resources vital for successful engagement with the institutions highlighted in section two above.

[1] See ARASA, Essential guide on Intellectual Property Rights and Access to Medicines in Southern and East Africa, available at https://www.arasa.info/media/arasa/Resources/user%20manuals/ip-toolkit-guide-1-2-print-edition.pdf

2. INTELLECTUAL PROPERTY NORMATIVE & REGULATORY FRAMEWORK IN MOZAMBIQUE

The Mozambican normative and regulatory framework on IP rights and access to medicines comprises international and domestic norms and policies speaking to the subject at hand.

At the international level, Mozambique subscribes to the following commitments on IP protection.

- United Nations General Assembly Resolution and *Political Declaration on HIV and AIDS: intensifying our efforts to eliminate HIV and AIDS*. (2011)
- Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.
- Global Plan for the Prevention and Control of Non-communicable Diseases (2013-2020).
- Agreement establishing the World Trade Organization (WTO) - Resolution 12 of 1996.
- World Trade Organization (WTO) - Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1994).
- Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Resolution 20 of 2007).
- Patent Cooperation Treaty - Resolution 35 of 1999.
- Convention Establishing the World Intellectual Property Organization (April 15, 1998).
- Paris Convention for the Protection of Industrial Property – Resolution 21 of 1997.

At regional and sub-regional level, the country subscribes to the following commitments on IP protection.

- African Union Roadmap on shared responsibility and global solidarity for AIDS, TB and Malaria response in Africa – 2012 (African Union).
- TRIPS Agreement and Doha Declaration on TRIPS and Public Health (African Union)
- Treaty establishing ARIPO – Resolution 34 of 1999 (African Regional Intellectual Property Organisation – ARIPO).
- Pharmaceutical Business Plan - 2015-2019 (Southern African Development Community – SADC) currently under review.

At national /domestic level Mozambique has a robust legislative framework protecting IP rights.

The main instruments protecting IP rights in Mozambique include:

(a) the Industrial Property Act (Decree No. 47/2015);
(b) Regulation governing activities of Intellectual Property Agents (Decree No. 19/1999);
(c) the Statutes governing the establishing of the Industrial Property Institute (Decree No. 50/2003); and
(d) Act on the Protection of the Rights of Authors (Act No. 4/2001).

The Industrial Property Act is the main instrument regulating IP rights in Mozambique. The Act is divided into six Chapters. Chapter one sets out basic concepts and defines the object and ambit of application of the law. Chapter two sets out the IP regime including protection of IP rights including the process for obtaining patents, licensing or registration of trademarks and other IP rights. Chapter three lists IP offenses and Chapter four speaks to the fees related to IP rights and applications. Chapter five and six deal with the Intellectual Property Gazette and Transitory provisions, respectively. Key to this Advocacy Toolkit, the Mozambican IP regime incorporates some TRIPS flexibilities. The definitions of the main IP rights protected and the details of these flexibilities as covered in the law are discussed jointly below with view to highlight the advances and the gaps in IP rights and access to medicines in Mozambique.

What is property?

Generally, property is “the right to the exclusive ownership and control of a specified object” or thing. The legal definition of property does not focus on the object itself. Rather it focuses on “the relationship that an individual or a corporation has with the object and with the rest of the world in relation with the object. Property is therefore defined as a relation. There are two types of relations: property that exists; corporeal (property/relation) and incorporeal property/relation.

Corporeal property

Is the right to ownership of material things. In corporeal rights the thing owned may be seen and/or handled such as a building or a car.

Incorporeal property

Is the right to ownership of intangible property such as patent rights, lease or mortgage.

What are intellectual property rights?

Intellectual property rights are rights conferred by law over innovations and other creations of the mind. Intellectual property rights are similar to other category of property rights. The creator of intellectual property is usually entitled to the enjoyment of time-limited exclusive rights over the utilization of his or her property. The Universal Declaration of Human Rights (UDHR) recognizes intellectual property rights as human rights (see Article 27/2 of the UDHR). In sum, Article 27/2 of the UDHR sets out that "everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

What is meant by the "territorial nature" of Intellectual property rights?

Intellectual property rights are granted by a state's national institutions (e.g. patent office) and are valid only in the territory of the country issuing or recognizing IP rights and only for a limited period of time. They are viewed as 'territorial' in nature, as they are bound by that country's national laws and policies.

What is a patent?

A patent is an exclusive right that the IP authorities of a state grant to an inventor over an invention. WIPO defines an invention as "a new product or process that solves a technical problem." Inventions differ from a discovery on the basis that a discovery is something that already exists in nature, but had not been found by persons with skills in a relevant discipline.

Patentability criteria in Mozambique IP regime

The patentability criteria under Mozambique's Industrial Property Act meets the patentability standard enshrined in the internationally acclaimed TRIPS Agreement. Thus, in line with article (27(1) of the TRIPS Agreement article 32 of the Industrial Property Acts sets out that an invention is patentable of it is *new, involves an inventive step,* and is *capable of industrial application*. In terms of the law, patents are protected for a period of 20 years. [2]

[2] See See Article 73(1) of Decree No. 47/2015.

Exclusion from patentability

Article 38 of the Industrial Property Act prohibits patentability of inventions that are contrary to public order and morality, and the protection of human, animal, plant and environmental health. The law also bans patentability of any such inventions relating to the discovery of plants and animals, or parts of such plants or animal, and the biological processes employed for the acquisition of such plants of animal.[3] The banning/ exclusion of patentability of inventions that are contrary to human health is a welcome development in that it meets the standards enshrined in the TRIPS Agreements, which seeks to ensure access to essential medicines including treatment for HIV/AIDS. *The law could be improved by explicitly excluding patentability for medicines, particularly essential medicines such as anti-retroviral treatment.*

Patent opposition

In article 68 of the main IP law anyone who may face damage with the granting of a patent can challenge the patent application. According to the law, challenge must be lodged within 60 days following the publication of the patent application on the Industrial Property Gazette, the official news Bulletin of the IP authority. There is a fee associated with challenges or oppositions to patents brought within the 60 days highlighted above. Additional fees apply where the opposer requests for an extension of the timeline to lodge the challenge. In the latter scenario the authorities may award no more than 60 days to any opposer who applies for extension of the timeline of lodging an opposition provided that the competent fees are paid.[4]

It is concerning that only persons who may face damage[5] can oppose patent application. The law must be revised to include other key role players such as civil society organisations who are better placed to challenge patent applications that may limit access to essential medicines.

The payment of a fee for challenging patent application and payment of fee for requests of extension of the deadline prescribed for lodging challenges against a patent application must be revoked as it may prevent oppositions against the patentability of essential medicines. The situation is exacerbated where interested opposer lacks the funds needed to pay fees associated with extension of the deadline prescribed for patent opposition.

[3] See Article 38 (2) (a) and (b).

[4] See Article 68(2).

[5] Although this is raised as a concern, the author of this report could not find evidence of any reported case when opposers beyond those facing damaged with the granting of a patent, where dined the opportunity to submit challenge when they found it relevant to oppose a patent application.

What is a trademark?

A trademark is ‘a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises.’ Trademarks are varied in nature and can take the form of a label, signature, word, letter, sign, brand or even combinations of these. Trademarks originated in ancient times when artisans used to distinguish their goods from others using marks and or signatures.

What is copyright?

Copyright is ‘a legal term used to describe the rights that creators have over their literary and artistic works. Copyrights cover rights over the creation of a range of items including books, music, paintings, sculpture and films, computer programs, databases, advertisements, maps and technical drawings.

The rights and duties of IP rights holders/owners

There are certain rights and obligations accorded holders of IP rights. Relevant to this Toolkit the rights and duties of patent holders are discussed for the impact they have on access to safe treatment and medicines.

What are the rights of a Patent holder?

A patent holder can transfer his/her rights to others. Patent holders have the right to exclude others from using, selling, making and importing the patented object. If any other person deals in a manner that violates any of those rights, the patent holder has the right to institute a legal action or claim against the perpetrator with view to enforce their rights. Depending on national laws, the patent holder may be afforded remedies including injunctions to stop the unlawful conduct and a right to payment for damages. These can be granted by courts.

What are the duties/obligations of a Patent holder?

It was mentioned above that IP rights provide the IP right holder with a number of protections including the right to use the IP, the right to sell or transfer the IP, and the right to stop others from using it. The exclusive rights, which IP rights confer upon the holder of an IP rights, effectively creates a legal monopoly on the owner without placing a duty on them in relation to others.

3. UNDERSTANDING THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

What is TRIPS Agreement?

The TRIPS Agreement is a treaty that incorporates and builds upon the latest versions of the primary intellectual property agreements administered by the World Intellectual Property Organisation (WIPO). In concrete terms TRIPS incorporates and elaborates on the standards of the Paris Convention for the Protection of Industrial Property, and the Berne Convention for the Protection of Literary and Artistic Works. These two instruments were considered as the primary agreements on intellectual property that date back to the 1880s. The TRIPS Agreement is unique in that it is part of a whole and indivisible package of agreements establishing the WTO which members must subscribe to before being admitted as members. In other words, states become parties to the TRIPS by mere signing of the agreement establishing the WTO conferring them membership.

The TRIPS is also known as a minimum standards agreement. It enjoins members to incorporate into their law's minimum standards for the protection and enforcement of intellectual property rights, namely copyright, patents, trademarks, geographical indications, industrial designs and undisclosed information. This means that countries that are WTO members are required to modify their laws in order to align them with the minimum standards stipulated in the TRIPS.

How does the TRIPS agreement affect access to medicines?

The TRIPS requires States to protect intellectual property rights in their respective jurisdiction. This led to the globalization of intellectual property rights under the TRIPS agreement which in turn caused a situation whereby patents and other forms of intellectual property perform an unprecedented and critical role in determining the availability and affordability of medicines. The problem with the TRIPS agreement is that it limited the freedom that countries had to design IP systems in ways that were most suitable to their public health priorities. It attempts to impose minimum standards of IP protection on all countries regardless of their level of development and technological capabilities. Consequently, the population in many developing countries that implement TRIPS standards face challenges accessing medicines.

4. SOME KEY CONCEPTS LINKED TO TRIPS: EVERGREENING, TRADE AND TRIPS PLUS

What is Evergreening?

Evergreening is a concept used to describe a tactic employed by (patent) holders of intellectual property rights, and particularly pharmaceutical companies, to extend patent protection around their respective branded medicines beyond the standard 20 years (prescribed by law). Often this is achieved by making even minor improvements/ modifications to the Active Pharmaceutical Ingredients (API) so that the patent holder of the protected product can apply for secondary patents (on the modified or improved product) which in effect will extent the standard 20-year protection. Countries like Argentina have developed anti-evergreening guidelines that are used by patent examiners to prevent granting patents on minor modifications of substances that are already known.

What is the problem of evergreening?

Not all IP offices in the world have the capacity to examine patent applications involving complex technologies. As a result, there is danger that patents may unintentionally be granted for substances that do not satisfy the requirements of patentability. From a public health perspective failure to scrutinize patents properly may lead to an increase in the grant of undeserving patents. These patents may end up obstructing access to medicine.

What can governments do to fight the evergreening tactic?

States may pass laws that exclude from the definition of inventions pharmaceutical derivatives or new forms of existing medications. India, for example, has a provision in its IP laws that exclude minor variations of a drug from patentability if the variation does not result in the enhanced efficacy of the product. Several Eastern and Southern African countries also exclude the mere adding of mixtures (*admixture*) of existing drugs from patentability. Under this exclusion, fixed dose combinations of existing drugs, including ARVs, may not be protected by patents.

What can CSO's do to prevent evergreening?

As a general rule CSOs play a key watchdog role as monitors of activities of the government. The society, and particularly CSOs forming the object of this Toolkit, must remain vigilant and act as appropriate to avoid patent evergreening. This may need CSOs to gather information about patent applications and study these applications to preventing that applications falling in the evergreening category are granted. Patent opposition is a good tool that can be employed to challenge applications falling in the evergreening category. CSOs can also advocate and lobby for legislative reforms, where there are no laws excluding substance improvements/modifications/derivatives from the definition of inventions.

5. HOW TO ENABLE ACCESS TO AFFORDABLE MEDICINE

Understanding the TRIPS flexibilities

Earlier it was said that the TRIPS agreement obliges member states to comply with minimum standards of IP protection. However, there are exceptions allowing member states of TRIPs not to implement TRIPS standards on IP protection, particularly when dealing with health and developmental issues. These exceptions to are known as TRIPS flexibilities. There is no clear definition of the term "flexibilities." Some have defined it 'as a range of rights, safeguards and options that WTO Members can exploit in their implementation of the TRIPS Agreement.

Flexibilities provided in the TRIPS and beyond?

The TRIPS agreement requires that patents should be granted to inventions that are new, inventive, and capable of industrial application. However, it does not provide definitions for these terms. Members thus have flexibility to determine what is new or inventive or useful within their territories. This flexibility can be exploited by members to achieve public health objectives. Members can adopt very strict interpretations of these terms in order to exclude undeserving inventions from patentability and promote access to medicines.

Article 8 of the TRIPS agreement also provides that "members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio- economic and technological development, provided that such measures are consistent with the provisions of this Agreement." Reading this provision, it is clear that States can deviate from TRIPS standards when such deviation aims to protect public health and nutrition as well as to promote certain matters in the interest of the public, particularly when such interest relates to sectors that are of paramount/vital importance to states (socio-economic and technological) development.

Waiver or transition period for Least Developed Countries (LDC waiver)

The most used flexibilities under the TRIPS is the Paragraph 7 mechanism (LDC waiver). This flexibility gives least developed countries (LDC states) the opportunity not to grant or enforce pharmaceutical patents. During the waiver or transition period LDCs that seek to ensure access to medicines for their populations can postpone the granting of patents for medicines. This option is only available for LDCs. [6]

[6] Comfort letters - A number of LDCs have introduced the practice of writing comfort letters to procurement authorities and generic suppliers indicating they were taking advantage of paragraph 7 (on TRIPS) flexibility not to enforce patents. Some take a short cut of simply issuing procurement letters stating that 'the government approves procurement of a generic medicine irrespective of its IP status.' However, it is not good enough to say merely that LDCs are exempted from implementing TRIPS. The fact that LDCs do not have to enforce pharmaceutical patents is not self-executing. The transition period gives LDCs freedom to choose whether or not to protect trademarks, patents, geographical indications or other IP rights. If they choose to protect IP then they have to apply the provisions on nondiscrimination.

Compulsory licensing [7]

The second most used flexibility is compulsory licensing which is an administrative act by which the government authorizes other entity or party to utilize an invention without the permission of the holder. The license overrides the rights of the holder over his invention in the public interest. The public interest might include access to medicine. If the government decide to authorize itself, it is called 'government use'. Under the TRIPS Agreement countries are free to determine the grounds on which a compulsory license should be issued (see Article 31 of the TRIPS). Patent holders still have the right to be compensated for the use of their patent rights by competitors and generic producers have to pay royalty on the sales of the generic versions of the medicines made under the compulsory license. Compulsory licences may be granted for different purposes including for local production, for import or for export. For instance, in Africa Ghana, Eritrea, Zambia, Mozambique and Zimbabwe have issued compulsory licenses for generic ARVs.

In the Mozambican context, Article 92 is the main provision in the Industrial Property Act regulating compulsory licenses. It states that "[t]he Minister that oversees the Institute of Intellectual Property may, on grounds of public interest, authorize the use of an invention without prior consent of the patent holder". This provision should be interpreted in a sense to mean that 'compulsory license' maybe be issued when there is a need to meet public interest.

In order jurisdictions compulsory licenses have also been used for 'importation of patented products by Government or a third party' and *for failure to exploit a patent*. [8] **The gap in the Mozambique IP law is that there are no possibilities to use compulsory licenses when the patent holder fails to explore his/her rights over a patented product. This, too, needs to be addressed.**

Exclusions or exemptions from patentability

Article 27(1) of TRIPS agreement gives members flexibility to define what constitutes an invention. For example, substances that already exist in nature may not be patentable because they do not fall under the definition of invention.

It is submitted therefore that under article 27(1) of the TRIPS patents are only available for inventions. Products or processes that cannot be classified as inventions are not eligible for patent protection. It is imperative that WTO members 'make full use of the policy space available in article 27 of the TRIPS agreement by adopting and applying rigorous definitions of invention and patentability that are in the best interest of the public health of the country and its inhabitants.'

[7] In IP language there is also the term '**voluntary licensing**' as opposed to '**compulsory license**'. Voluntary licensing does not fall under the category of flexibilities. It is a business strategy of companies. It sometimes determines whether a compulsory license should be issued or not.

[8] See sections 32 and 33 of the Botswana Industrial Property Act (Act No. 8 of 2010). See, also, Tapiwanashe Kujinga, (2015) *'An analysis of intellectual property legislation and policies in Botswana, Mauritius and Zimbabwe'*, research report commissioned by SAPAM, Pty (copy on file with the author).

Parallel importation

The TRIPS Agreement encourages parallel importation of products protected for IP purposes. Parallel importation means an interested party can import a product protected for IP purposes in another country where the inventor or patent holder also enjoys IP rights relating to the such product. The result is that the interested party and the inventor or patent holder commercialize the product in the same jurisdiction/country where the investor or patent holder also enjoys IP protection in relation to that product. In concrete terms, parallel importation or "exhaustion" refers to the importation, without the authorisation of the patent holder, of a patented product which has been placed on the market in a different country by the patent holder. This normally happens when the product in question is cheaper in that other market. Pharmaceutical companies offer their products at different prices in different jurisdictions. In this regard, it is sometimes cheaper to source products from an external market than procure them locally. This does not amount to infringement of the patent rights since the owner of IP right is already awarded protection in the first market. However, TRIPS gives States flexibility to determine whether parallel importation is permissible in their jurisdictions or not.

Other Flexibilities (exceptions to TRIPS)

Members of WTO are expected under article 41 of the TRIPS to ensure that they put in place enforcement procedures for IP laws. The idea is to ensure that effective action is taken against IP infringement. The procedures should also ensure the availability of sanctions which prevent and deter further IP infringement. However, there are some exceptions to this rule.

What types of exceptions are available?

Article 30 of the TRIPS, also known as Bolar Provision, set out that provided certain conditions are met, WTO members may allow manufactures of generics '(…) to start producing test-batches of a product before the patent expires, in order to collect the necessary data for submission to the registration authorities; this will reduce the delay for generic products to enter the market after the patent has expired…and thereby enhance competition.' The nature and scope of the exception (or research exception) vary significantly from country to country.

Another exception concerns the possibility given for WTO members to include in their IP rights protection regime an 'experimentation clause, which allows companies, universities and other research institutions to (carry out) experiment with patented inventions. Such experimentation may lead to new innovations, to improvement of existing inventions or to the realization that the granting of a patent was not justified and that it should be revoked.'

6. BEYOND TRIPS: THE DOHA DECLARATION

What is the Doha Declaration?

In 2001 States adopted the Doha Declaration of 2001 which agreed that countries can put health above trade if pharmaceutical patents are blocking access to medicines. The Declaration recognized the gravity of public health problems affecting developing countries, especially HIV/AIDS, TB Malaria and the "importance of creating a positive, mutually reinforcing link between the IP system and access to medicines." It made it clear that the TRIPS does not and should not prevent members from taking measures to protect public health and that it should be interpreted in a manner supportive of public health further. The gist of the Doha declaration is to put patient rights before patent rights, to make the TRIPS agreement more development friendly. With the Doha Declaration member states retain important policy options, flexibilities and safeguards to facilitate access to medicines. Notable, however, the Doha Declaration is a political statement (non-binding), which is not a legally binding document and should be used as a reference point for public health-friendly interpretations of TRIPS if disputes arise."

7. THE RELATIONSHIP BETWEEN HUMAN RIGHTS, INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES

What are essential medicines?

The World Health Organisation defines essential medicines as being the drugs 'that satisfy the priority health care needs of the population... selected with due regard to public health relevance, evidence on efficacy and safety and comparative cost-effectiveness… [and] intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.'

What is the link between IP and access to essential medicines?

IPRs in general and patents in particular are a tool for ensuring that the public benefits from human ingenuity. However, strict protection and enforcement of IPs can undermine access to essential medicines because they are tools that right holders use for extracting monopoly prices from the market.

What is a human rights-based approach to intellectual property and access to medicines?

A human rights-based approach to IP and access to medicines is a conceptual framework that seeks to analyse the global inequalities, which lie at the heart of access to medicines problems and the impact of IPRS on access through the prism of human rights. A human- rights based-approach argues that people have a non-negotiable right of access to medicines and imposes an obligation on States to remove all barriers to access, including IP related barriers.

What tools can be used to advocate for access to medicines?

The language of human rights provides a valuable framework for addressing access to medicines problems. This is because it exposes the conflict between the rights of property owners and the rights of vulnerable groups and the public interest. The human rights language attempts to strike a balance between the rights of property owners and members of the wider public.

Framing IP issues and access to medicines as human rights issues has many advantages as follows:

- The human rights language can be deployed as a useful tool for influencing international debates and negotiations on trade, IP and access to medicines. This is because of the legitimacy associated with human rights causes.
- Human rights add moral authority to advocacy around access to medicines.
- Human rights have a clear framework for assessing whether States are complying with their core minimum obligations, namely whether medicines are available, accessible, acceptable and of good quality.
- It emphasizes the point that IP should not only be a trade issue but also a human rights issue.

8. MAKING CSOs ADVOCACY PLAN ON INTELLECTUAL PROPERTY & ACCESS TO MEDICINES IN MOZAMBIQUE

What should CSO's consider when they are making an advocacy plan on Intellectual Property and Access to Medicines in Mozambique?

Selection of issues?

o CSOs need to select the main issue that they want to address whether it is a gap in Mozambique IP laws, policy or regulatory framework or if there is a challenge implementing the law, for example. The issue selected must be aligned to the following:

o The organisations Country Strategic Plan;

o Internal regional and global priorities on access to medicines for the population in the country.

o Based on the (issue) context where Plan has the biggest impact.

Analysis of the national economic, political, environmental, social and policy context:

o **What is the national context impacting on this issue?**
For instance, are there private stakeholders influencing access to medicines either by practicing high prices or making it difficult of the general population to access drugs treatment.

o **What is the specific issue context?**
For example, the current IP regime contains barriers to access to IP as it does not include flexibilities that would enable the government to ensure safe access to adequate and affordable medicines

o **What are others doing on this issue?**

o **Opportunities for influence**
For example, is the country going though legislative process targeting the IP regime?

Define the advocacy objectives based on the analysis (being as specific as possible)

o It is important that from your analysis you identify who, what, when and why.

Power analysis:

o Who are the individuals, organizations/institutions who hold the power to bring about the desired change? CSOs can consider working with duty bearers in government or IP authorities, policymakers including parliamentarians and or the individuals lacking access to medicines themselves. In all events it is important to use the human rights frame of do no harm to the persons most affected gaps in access to medicines caused by protection of IP rights.

o Who are the key opinion leaders, media outlets and broadcast and radio. These should be used to disseminate messages.

o Opponents - who are the individuals, organizations/institutions and civil society groups who may oppose or actively block your efforts?

Timeline:

o Define a timeline or time frame to influence the change. Sometimes there may be need to extend the time frame depending on the outcomes of the advocacy activities implemented. Consider whether or not there is one specific opportunity/event or decision to explore or if there are other forums.

o Define what are the activities that need to carry out over the period of time elected for advocacy.

Tactics:

o CSOs need to consider if they need to partner with (local/international) organizations? If so, identify which organisations and the role their role?

o Plan carefully how to involve the affected persons in advocacy, and particularly those lacking medicines or treatment.

o Identifying specific opportunities within the timeline

Evidence based:

o CSOs must back their respective advocacy plans with evidence. They should consider, what evidence is required to push their arguments in advocating for the change/s. This may need them to develop studies and prepare key messages and policy asks? (Evidence could include external research and data and internal programme evidence, data and research)

o For example, the ARASA's 2019 study analysing the Intellectual Property legal and regulatory framework and access to Medicines in Mozambique contains good recommendations for advocacy (see pg. 10 of the ARASA study).

Draft communications plan and key messages:

o CSOs can integrate communication techniques into the advocacy plan/timeline – they can also use social media, press work (press releases, press conferences etc.) to push advocacy messages.

o CSOs may need to develop key messages. Key messages should be compelling to influence key actors/target groups identified in the section dealing with power analysis (see above).

Risk Assessment:

o CSOs may like to consider if there are risks linked to carrying out the advocacy work. This may include the need to list/identify as many risks as possible and outline mitigation activities to limit and manage risks in the event they occur.

Resources:

o Each organisation needs to identify what support from teams and individuals in their respective organisations/offices, regional office and from across they will need to carry out the advocacy work.

o It is important to consider how each organisation will manage the advocacy work and where organisations chose to work together they should also consider how they will manage the work. In some cases this may entail the setting up an internal working group for example.

o What is the budget for this work?

9. SOME ADVOCACY FORUMS

CSOs can implement advocacy on IP rights and Access to medicines at the local level as well as at the international global, regional, and subregional levels.

Advocacy at the local level

At the local level it is possible to find institutions with a mandate on IP and other that have mandate on human rights issues overlapping with IP rights. Examples of these include the IP authorities, the Parliament, and the Human Rights Commission.

Exploring some of the advocacy opportunities for CSOs available at the IP office

The IP office receives local and international applications for patents and other IP rights. Working with the IP office may help to make early detection of applications not deserving IP protection including prevent evergreen patent applications.

As the principal institution tasked with IP protection, the IP office plays a crucial role in advising government on IP matters. CSOs may elect to work with IP office on its advisory role to raise with government the urgent need for the country to use flexibilities provided for under the IP law in force.

Many IP offices are not equipped with staff that understand human rights issues. The IP Office in Mozambique is no exception. CSOs may play a key role in strengthening the human rights capacity of IP office, and particularly the link between IP and access to medicines. The work should include ensuring that IP Office keeps up to date with impact of (pharmaceutical) patent applications done though ARIPO regional office.

Advocacy at Parliament

Parliament exercises the law-making function. CSOs may engage with Parliament to raise concerns over gaps in the domestic IP laws and to lobby for stronger protection for health rights and particular for access to medicines over and above the protection given to IP rights.

In democratic systems premised on the principle of separation of powers. Parliament monitors the activities of the executive. In exploring the role of the Parliament in monitoring government activities, CSOs may lobby for improved access to safe medicines and treatment in a context where public hospitals are lack essential medicines for patients.

Advocacy at the Human Rights Commission

What is the role/function of the Human Rights Commission?

Function – The National Human Rights Commission is tasked with monitoring of human rights. It provides technical support on human rights matters in law making processes and reports to the President about human rights in the country.

Exploring advocacy at the Human Rights Commission

CSOs can work closely with the Human Rights Commission supporting the Commission in its duty on legislative review on matters concerning challenges deriving from IP protection on access to medicines in the country.

Within the Commissions mandate to monitor human rights in the country, CSOs can invite the Commission to visit health centers and inquire about the situation of access to medicines and treatment and request the Commission to make recommendations to health authorities to address the lack of medicines including exploring flexibilities in the country's IP norms to ensure that essential medicines are made available.

Advocacy at the International Level

Advocacy at the international level is mainly through institutions with IP mandate and through mechanisms tasked with the promotion and protection of human rights and particularly human rights mechanisms tasked with the protection and promotion on the right to health, including the UN treaty bodies.

Treaty body: Composition, function and or mandate

The term treaty bodies is used to describe the institutions established under a treaty to monitor its implementation. There are as many treaty bodies as there are human rights treaties under the United Nations human rights system. Thus, implementation of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) is monitored by a Committee of experts called the CEDAW Committee. The United Nations Convention on the Rights of the Child is monitored by the Children's Rights Committee and so on and so forth.

Often treaty bodies comprised of 10 to 23 members (average 18). The members of treaty bodies elected to serve as independent experts, they are chosen among individuals of high moral standing who are competent in the relevant area of human rights for the treaty they monitor and they serve in their personal capacity and not as nationals of a particular country. The term of office of members in most treaty bodies is 4 years.

What are the main functions of treaty bodies and advocacy actions that CSOs can implement?

The main functions of treaty bodies and examples of some advocacy actions that CSOs can implement are summarised below:

Treaty bodies examine State Party reports (initial and periodic)

o CSOs can submit shadow reports to treaty bodies raising the situation of access to medicines in regard to a specific human right (whether as a matter of children's rights for example or in the context of the rights of persons with disabilities and so on and so forth) monitored by the particular treaty body.

o CSOs can use treaty body recommendations such as recommendations speaking to IP protection which derive from the examination of the official report of the State to advocate and lobby at domestic level for greater access to medicines.

Treaty bodies receive individual complaints /Inter-State complaints

o CSOs can submit complaint regarding IP protection regimes that violate specific human rights, and particularly the right to health.

Treaty bodies are tasked with interpretation of the treaty (General Comments)

o Advocacy may include CSOs contributions to the process of development of general comments. During this process CSOs can favour interpretations supporting the right to health and particular access to medicines against IP protection in national laws and policies.

Treaty bodies follow up (implementation)

o CSOs can provide feedback and or updates regarding the general situation of access to medicines and safe treatment linked to treaty bodies follow mandate in respects of implementation of the standards contained in human rights instruments protection the right to health.

10. USEFUL CONTACTS & RESOURCES

IP and patent opposition as well as links to the documents on potential COVID-19 treatments

https://drive.google.com/drive/folders/1Dwsb6C2cVi3ip1BJNTj7L0U258zFnbyi?usp=sharing

https://drive.google.com/drive/folders/15vJ8_xGdmP2AeYyxI-iFb0_liS4UFAPF?usp=sharing

https://drive.google.com/drive/folders/161Srr0n8FCYGqpGFL-fN9OrhggH5iSjS?usp=sharing

https://drive.google.com/drive/folders/1vvfSN0Y5JLNRhXV9aYknc8ruZbqVdYEf?usp=sharing

https://drive.google.com/drive/folders/1OalDvU5qiRyiraFmfSG5Jxgt_W5LaVFK?usp=sharing

https://drive.google.com/drive/folders/119rxscc3bOf-3OMPvLtg8n47SvD4YN6L?usp=sharing

https://drive.google.com/drive/folders/1G1e8E5RBWqLm5w4RTHkPXTe-_Z8zgxEl?usp=sharing

Link to ARASA partners in Mozambique

https://www.arasa.info/our-partners/mozambique

BREAKING IP BARRIERS
Creating Pathways to Medicine Access

ARASA
AIDS & Rights Alliance for Southern Africa

SAPAM
HEALTH SYSTEMS STRENGTHENING