Essential Guide

ARASA
AIDS & Rights Alliance for Southern Africa

Intellectual Property Rights And Access to Medicines in Southern and East Africa

BREAKING IP BARRIERS
Creating Pathways to Medicine Access

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INTRODUCTION

Intellectual Property Rights (IPRs) have had a significant impact on global access to sustainable availability and access to affordable, quality, safe and efficacious essential medicines and diagnostics. Particularly, intellectual property law has played an increasing role in determining how medicines are developed, and how they can be accessed.

Within the African context, the HIV, TB, malaria and hepatitis B and C disease burdens are among the highest in the world, thus increasing the need for essential medicines for the African population. However, intellectual property rights continue to undermine access to diagnostics, medicines, and other health related technologies for Africa and the rest of the developing world. Understanding the linkages between intellectual property rights and access to essential medicines thus becomes a critical one for civil society groups.

Intellectual property rights are territorial or national in nature. They are generally created and defined by national laws and apply only in the territory of the country concerned. In order to encourage creators or inventors to disseminate their works beyond their borders countries have adopted international agreements to protect such creations or inventions. These agreements may either be bilateral or multilateral in nature. By way of harmonising IPR globally, the WTO developed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

This Essential Guide provides an introduction to intellectual property rights, how they are acquired and how IP laws and policies impact on access to essential drugs, diagnostics and other medical devices. For the purposes of this Guide, the term medicines will be used broadly to refer to all health-related technologies. These include drugs, diagnostics, vaccines and other health care products.

Why are we fighting this battle?

Access to medicines raises underlying moral, ethical and human rights issues. There is existing capacity to provide access to essential medicines across the globe. These medicines are widely available in the developed world. Yet millions of people in Africa are dying because they do not have access to these medical interventions. This represents a gross violation of human rights.

Purpose of the Guide

This guide aims to give the reader:

a) An understanding and appreciation of the intricate linkages between intellectual property rights and access to essential medicines;

b) Knowledge and awareness of the barriers presented by intellectual property legal and policy frameworks on access to medicines.

c) Increased knowledge around the use of the flexibilities provided for by international trade agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which can improve access to medicines at a domestic level.

The guide wishes to provide the reader, with an understanding of the role that intellectual property rights plays in access to medicines, and to provide entry points for the development of advocacy strategies to address these. It provides the user with tools for working with policy makers at a domestic level, to improve access to sustainable, affordable and safe essential medicines.

For Monitoring and Evaluation purposes we kindly request that you notify ARASA about any intended use of this essential brief. This will enable us to record its impact, and to keep you updated on any revisions or similar initiatives that we may undertake in future. As we are committed to constant improvement of our efforts, we also welcome any feedback, positive or negative. Should you require assistance with adaptation, translation and/or dissemination, we will try to connect you with organisations that may be able to support with this.

For further information on the toolkit, please contact lynette@arasa.info

1: WHO CONTROLS INTELLECTUAL PROPERTY RIGHTS GLOBALLY?

The World Intellectual Property Organization (WIPO)

WIPO is one of the specialized agencies of the UN, which has 184 member states. The WIPO main objective is "to promote the protection of intellectual property throughout the world through cooperation among States."[1] WIPO administers 26 international treaties and is based in Geneva, Switzerland.

The World Trade Organization (WTO)

The WTO is an international organization that governs trade between countries across the globe. The main objective of the WTO is to promote smooth, predictable and free trade between nations. The WTO is a body, which provides a framework within which governments negotiate trade agreements and settle trade disputes. Specifically, it is charged with the responsibility of facilitating international trade negotiations, handling trade disputes and monitoring domestic level trade policies. Apart from administering trade agreements, the WTO offers technical assistance to developing on trade-related issues.

African Regional Systems for granting intellectual property rights

There are two regional systems for granting intellectual property in Africa namely the ARIPO (African Regional Intellectual Property Organization) and the OAPI (Organisation Africaine de la Propriete Intellectuelle). These systems were established in order to provide for an inexpensive, efficient and convenient system for obtaining patents within some African countries. Some of the major economies in Africa including Nigeria, South Africa and Egypt are not party to the above systems.

2: UNCOVERING INTELLECTUAL PROPERTY RIGHTS

What is property?

The law has generally defined property as "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 that object."[2] Property is therefore defined as a relation. There are two types of property that exist; corporeal and incorporeal property.

- Corporeal property
    - Right to ownership of material things
    - May be seen and/or handled such as a building or a car.
- Incorporeal property:
    - Right to ownership of intangible property such as patent rights, lease or mortgage.

What are intellectual property rights?

Intellectual property rights (IPRs) are rights conferred by law over innovations and other creations of the mind. IPRs are similar to other category of property rights. The creator of intellectual property is usually entitled to time-limited exclusive rights over the utilization of his or her property.

Intellectual property rights are recognized as human rights by article 27(2) of the Universal Declaration of Human Rights. The article provides 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."[3]

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

IPRs are granted by a state's national institutions (e.g. patent office) and are valid only on the national territory 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 a limited exclusive right that governments grant to an inventor over an invention. The WIPO defines an invention as "a new product or process that solves a technical problem."[4] It distinguishes an invention 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.

Patents are covered by part II section 5 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS).[5]

What is a trade mark?

WIPO defines a trademark as "a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises."[6] Trademarks are varied in nature and can take the form of a label, signature, word, letter, sign, brand or even combinations of the above. Trademarks owe their origins to ancient times when artisans used to distinguish their goods from others using signatures or marks.

Trademarks are covered by part II section 2 of TRIPS.[7]

What is copyright?

WIPO defines copyright as "a legal term used to describe the rights that creators have over their literary and artistic works. Works covered by copyright range from books, music, paintings, sculpture and films, to computer programs, databases, advertisements, maps and technical drawings."[8]

Copyright is covered by part II section 1 of TRIPS.[9]

What are the rights or an IP owner?

Once a patent is secured they can license their rights to others, transfer them etc. They 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 owners have the right to institute an infringement action, to enforce their rights. Depending on the territorial laws, the owners are afforded remedies ranging from injunctions to stop the unlawful conduct to damages, which can be granted by courts.

What are the obligations of an IP owner?

Intellectual property protection entails a bundle of rights that are conferred on the intellectual holder of IPRs. These include the right to use the IP, the right to sell or transfer the IP, and the right to stop others from using the IP. The exclusive rights, which IPRs confer on the owner, effectively create a legal monopoly on the owner.

3: THE PHARMACEUTICAL SECTOR

What is the Role of IPRs in pharmaceutical sector?

The main rationale for providing patent protection for pharmaceuticals is to (i) award the invention and (ii) to incentivise the pharmaceutical industry to continue R&D as this is expensive and risky. Innovators of products and processes in the pharmaceutical sector, receive patents (generally for a time period of 20 years), to use the product or process, the right to sell or transfer the products and processes, at prices that they deem fit. They also have the right to stop others from using these.

Who controls the Global Pharmaceutical Market?

Statistics show that the global pharmaceutical market is worth US$ 300 per annum. It is predicted that this figure will rise to US400 billion within a period of three years. However, the global trade in Pharmaceuticals has historically been dominated by industrialised countries. Six of these companies are based in the United States of America, while four of them are based in Europe. Future projections suggest that North and South America, Europe and Japan will continue accounting for 85 percent of the global pharmaceutical trade in the foreseeable future.

What is the difference between generic and originator drugs?

There is no difference to the end user, the only difference is that the originator drug no longer is protected by a patent.

Why are access to generic medicines important?

They are more affordable than patented brand-name medicines. They facilitate access to medicines for people who need safe, inexpensive and life-saving medicines. They assist government to purchase medicines that would cater for a wider population than branded medicines.

What is the difference between generics and counterfeit/substandard medicines?

A counterfeit drug is a deliberate or fraudulent misrepresentation of either an originators or generic drug. A generic medicine is a drug that have the same active ingredient as the originator medicine.

Why is it that India is considered one of the biggest manufacturers of generic medicine?

Prior to 2005 India did not grant patents for pharmaceuticals companies because these patents were not deemed to be in the best interest of the public. Party because of this, several AIDS medicines were and are produced as generics.

What happens when medicines are patent-free (or off patent) and generic versions enter the market?

In most cases the price of the medicine for both the original drug and the generic drop dramatically as can be seen on figure 1.

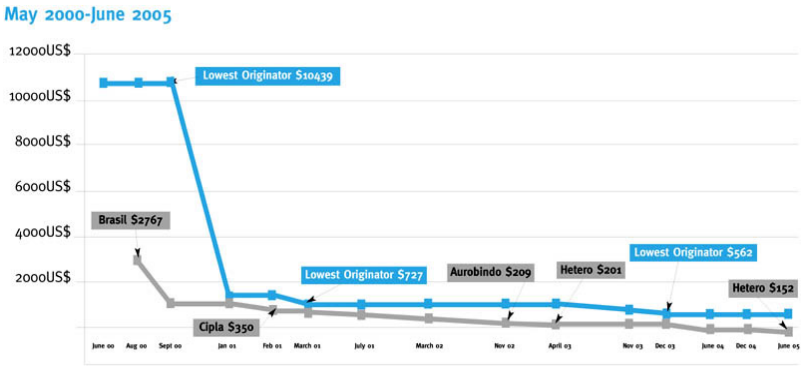

Figure 1.0 The effects of generic competition (Source: World Health Organisation, 2005)

Manufacturing of generic drugs are among the most effective ways of lowering drug prices.[10] "On average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price."[11]

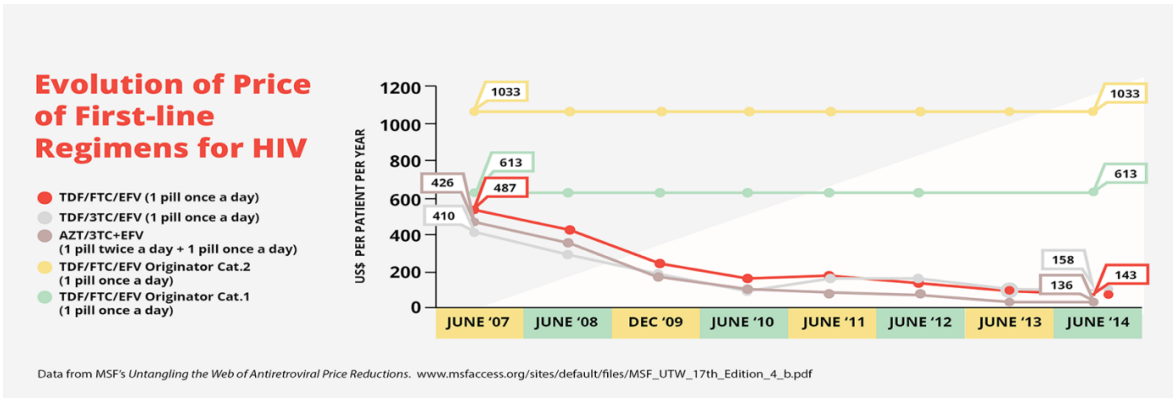

Figure 1.1 The Price of a Patent (Source: Health Action International, 2016)

Figure 1.1 gives a clear picture to the cost of generic version plummeting over the years, whereas the price of the branded drugs has remained constant.[12]

4: UNTANGLING RESEARCH & DEVELOPMENT

How much of the revenue is diverted into the development of new drugs?

The big pharmaceutical companies pose the argument that they need to charge high prices for their originator medicines because it takes of the high costs of R&D. Thus while these medicines are under patent, they will regulate access to these, while recouping the costs of R&D. Interestingly the pharmaceutical companies spend twice the amount of money on marketing than on R&D, which brings their arguments around R&D arguments under scrutiny – especially when some of these medicines are live-saving medicines needed in developing countries.

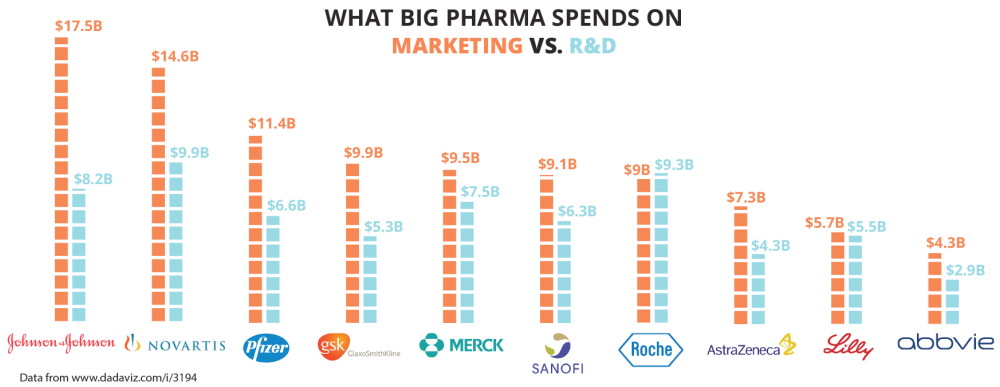

Figure 1.2 The Real Cost of R&D (Source: Health Action International, 2016)

How much do governments contribute to the development of new drugs?

This varies from country to country. One research showed that 10 percent of new medicines approved by the United States Food and Drug Administration () between 1990 and 2007 were discovered through public sector research. If we select medicines rated importance to health it jumps to 20 percent.[13]

5: TRIPS (trips us all)

What is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)?

The TRIPS Agreement came into force in 1995, as part of the Agreement Establishing the WTO. TRIPS incorporates and builds upon the latest versions of the primary intellectual property agreements administered by the WIPO, the Paris Convention for the Protection of Industrial Property, and the Berne Convention for the Protection of Literary and Artistic Works, agreements that go back to the 1880s. The uniqueness of the TRIPS Agreement stems from the fact that it is part of a whole and indivisible package of agreements that WTO members must subscribe to before being admitted as members.

The TRIPS is a minimum standards agreement. The Agreement obliges members to incorporate into their laws minimum standards for the protection and enforcement of copyright, patents, trademarks, geographical indications, industrial designs and undisclosed information. In other words, 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 globalization of IPRs under the TRIPS agreement has led to 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 irrespective of their level of development and technological capabilities.

6: EVERGREENING, TRADE AND TRIPS PLUS

What is Evergreening?

Evergreening is a tactic employed by pharmaceutical companies to extend patent protection around their branded medicines beyond the standard 20 years. By making even minor improvements/ modifications to the Active Pharmaceutical Ingredients (API) they can apply for secondary patents which in effect will extent the standard 20 year protection.[14]

Some countries like Argentina have recently developed anti-evergreening guidelines that are used by patent examiners to prevent granting patents on minor modifications of already known substances.

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 usually a danger that patents may unintentionally be granted 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 laws that exclude minor variations of a drug from patentability if the variation does not result in the enhanced efficacy of the product. A number of Eastern and Southern African countries also exclude “mere admixtures” of existing drugs from patentability. Under this exclusion, fixed dose combinations of existing drugs, including ARVs, may not be protected by patents.

What are Free Trade Agreements (FTAs)?

Free Trade Agreements are agreements between two or more countries adopted with the aim of reducing or removing trade barriers, and usually lead to the formation of trade blocs covering a defined geographic area. While FTAs normally focus on trade in goods and services, they can extend to other areas including IPRs.

What are Economic Partnership Agreements (EPAs)?

Economic Partnership Agreements (EPAs) are “trade and development agreements negotiated between the European Union (EU) and the African, Caribbean and Pacific Group of States (ACP). The stated aims of the EPAs are to promote trade as well as poverty reduction and sustainable

development for partner states. On 10 of June 2016 the EU signed the EPA with Botswana, Lesotho, Mozambique, Namibia, South Africa and Swaziland – the so-called "SADC EPA group".[15]

What or who regulates FTAs and EPAs?

They are generally regulated by the WTO, which is primarily concerned free trade across the globe.

How do FTAs and EPAs present an obstacle to the use of TRIPS flexibilities?

Most countries that do business with developed countries are members of the WTO and are thus obliged to comply with TRIPS. Unfortunatly EPAs have been used to pressure developed countries to adopt standards that are higher than those mandated by the TRIPs at the disadvantage of their citizens. The effect is that FTA's andn EPA's are threating to erode the flexibilities in the TRIPS agreement.[16] Such greater protection hinders the entry of suppliers of generic medicines on the market. This results in inflation of prices and limited access to medicines.

What are TRIPS-Plus standards?

TRIPS-Plus is not an official name, actually the TRIPS were created to protect against measures found in what has been dubbed "TRIPS-Plus". The TRIPS-Plus provisions require more strict IP standards than those found in TRIPS or that limit flexibilities inherent in TRIPS. In return for agreeing to such measures developing countries receives for example beneficial Free Trade Agreements (FTA).

Commonly found "TRIPS-plus" measures and terms found during trade talks:

- Extended patent terms (longer than 20 years)
- Patent linkage
- Provisions which limit the use of Compulsory Licences
- Restrictive generic competition
- Data exclusivity
- Investment clauses

The appearance of "TRIPS-Plus" measures came after the use of flexibilities by developing countries. Developed countries would like to see more stringent IP standards across the globe in order to protect the interest of their pharmaceutical companies. In brief, FTAs are used as tools for limiting the ability of developing countries to implement the Doha Declaration on TRIPS and Public Health.[17] These agreements may adversely affect access to and cost of medicines because they undermine the ability of States to take full advantage of TRIPS flexibilities.

How has TRIPS-Plus measures been used against generic medicines in transit?

A case in point is the now repealed 26 EU Council Regulation (EC) No.1383/2003 which targeted the importation; exportation and transit of all IP protected goods as long as these are found in the EU territory. The regulation was applied by Dutch customs officials to confiscate generic medicines from India in transit to Brazil, Mexico, Peru, Colombia, Nigeria and Equador. These medicines were otherwise legal in India and in their destination countries. Measures of this nature are obviously TRIPS-plus. In 2008 a total of 17 shipments holding generic medicines were seized by Dutch authorities.[18]

What is data exclusivity?

Data exclusivity is another TRIPS-Plus tool championed by some developed nations. It is a different type of monopoly on medicines separate from patents. It refers to the period during which the pharmaceutical test data is protected from drug regulatory purposes. This would then delay the registration and launch of generic medicine into the market.

What is the Anti-counterfeiting agenda?

Developed countries have also attempted to advance their TRIPS-plus enforcement agenda through promoting the inclusion of anti-counterfeiting provisions in developing country legislation. These provisions have generally adopted wide definitions of the term 'counterfeit' to include generics. This potentially hampers access to medicines.

Kenya for example adopted an Anti-counterfeiting Act, which contained a legal provision that equated generic medicines to counterfeits. The adoption of the law was funded by the EU. The provision was challenged by a coalition of Civil Society partners and has since been declared unconstitutional by the Court.

7: HOW TO ENABLE ACCESS TO AFFORDABLE MEDICINE

TRIPS flexibilities

Born out of the Doha Declaration of 2001 which agreed that countries can put health above trade if pharmaceutical patents are blocking access to medicines.

The TRIPS agreement obliges members to abide by minimum standards of IP protection. However, member states retain important policy options, flexibilities and safeguards to facilitate access to medicines. 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."[19] Countries are at liberty to adopt laws and policies that strike a proper balance between provision of R&D incentives and guaranteeing access to essential medicines.

What are the key flexibilities that are provided for in the TRIPS?

According to Article 8 of the TRIPS agreement which states 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."[20]

The most used flexibilities are the Paragraph 7 mechanism (LDC waiver). This flexibility gives LDC states the opportunity not to grant or enforce pharmaceutical patents. The second most used flexibility is compulsory licensing which is an administrative act by which the government authorize other entity or party to utilize an invention without the permission of the holder.

What is the Doha Declaration?

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."[21] 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. "It is a political, rather than a legal statement and should be used as a reference point for more public health-friendly interpretations of TRIPS if disputes arise."[22]

The TRIPS agreement contains a number of flexibilities that can be utilized by developing countries to

support or promote access to medicine:

1) Waivers or transition periods

The first flexibility that is available to governments that seek to ensure access to medicines for their populations is to postpone the granting of patents for medicines. This option is only available for LDCs.

2) Exclusions or exemptions from patentability

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."[23]

What does article 27(1) of TRIPS say about exclusions?

The 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.

What are the obligations of WTO Members and the TRIPS?

All countries who are members of the 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 prompt which prevent and deter further IP infringement.

What types of exceptions are available?

For (generic) manufactuers there is the **Bolar provison** which allows (provided certain conditions are met) "manufacturers 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."[24] The nature and scope of the excemption (or research excemption) vary significantly from country to country.

Bolar Provision is covered by Article 30 of the TRIPS.[25]

Another exemption is the "**experimentation clause**, which allows companies, universities and other research institutions to 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."[26]

Experimentation clause is covered by Article 30 of the TRIPS.[27]

8: HUMAN RIGHTS, INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES

What are essential medicines?

According to the WHO, essential drugs are "those 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."[28]

What is the linkage 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 medicine problems. This is because it exposes the conflict between the rights of property owners and the rights of the poor and the public interest. It accordingly attempts to strike a balance between the rights of property owners and members of the wider public.

Framing the issues of IP and access to medicines as human rights issues has a number of advantages:

- 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 seen as a trade issue but also a human rights issue.

What is resolution 141?

It is a resolution of the African Commission on Human and People's Rights adopted in 2008. The resolutions can be used as tools for reminding States of their specific commitments and obligations pertaining to access to medicines by taking concrete action to promote the use of TRIPS flexibilities. They can thus be used as advocacy tools for access to medicines in Africa.

The resolution:

- Recognizes the right "to enjoy the best attainable standard of physical and mental health that is guaranteed by Article 15 of the African Charter on Human and People's Rights.
- Recognizes the obligation placed on States to ensure that everyone has access to medicines.
- It calls upon States to take measures aimed at guaranteeing the availability, accessibility (including affordability), quality and acceptability of medicines.
- The resolution urges States to:
- Refrain from implementing IP policies that do not take full advantage of the flexibilities provided for under the TRIPS agreement to promote access to medicines.
- Utilize IP, competition and consumer protection law as tools for stimulating access to medicines.
- Promote meaningful public participation in decisions that are related to access to medicines, including patenting decisions.

9: GOVERNMENT ROLE IN ACCESS TO MEDICINE

What should the government do when India can no longer produce generics?

Government role in access to medicine is going to become more crucial as all the post-2005 patented medicines can no longer be accessed from India in the form of cheap generics. This is unless the patent should be deemed invalid or refused or compulsory license or government use is issued.

How can the exit of India as a generic exporter be a good thing?

With the exit of India as a generic exporter, companies in LDC of East and West Africa can take advantage and produce generic medicines since the LDC status allows these countries to disregard the TRIPS agreement until 2021, furthermore they can ignore pharmaceutical patents until 2033.

How can a government go about setting and applying strict patentability criteria?

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.

What is compulsory license or government use?

A compulsory license is an administrative act by which the government authorize other entity or party to utilize an invention without the permission of the holder. It permits the production, importation or sale of a patented product without the approval of the patent holder.

The licence 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. 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 local production, for import or export.

In Africa for example, Ghana, Eritrea, Zambia, Mozambique and Zimbabwe have issued compulsory licenses for generic ARVs.

Article 31 of the TRIPS relates to use:

- By the government
- On behalf of the government
- By third parties authorized by the government

Compulsory licensing and **government use** is covered by Article 31 of the TRIPS.[29]

How can Paragraph 6 be used to assist in access to medicine?

The compulsory licensing for export provision (Paragraph 6 system) endeavors to solve the problem of insufficient manufacturing capacity by attempting to harness economies of scale using regional trade blocs. It exempts developing countries or LDCs that are members of regional trade agreements; at least 50% of whose membership comprises LDCs, from certain TRIPS obligations. One obligation they are exempted from is **Article 31(f)**; which only allows countries to issue Compulsory Licenses to authorise manufacture of pharmaceuticals predominantly for domestic use. Exports are only allowed in limited quantities.

Due to it being seen as cumbersome to use, it has only been used once (as of 2016), by Rwanda in 2007 after four years of negotiations and red tape and financial loss for the Canadian generic manufacturer Apotex. Ellen 't Hoen says instead of revision there is the option of the Paragraph 6 "regional waiver of the mechanism provides options for effective use of compulsory licensing by creating economies of scale."[30]

What are 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 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."[31]

However, it is not adequate merely to say 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 etc. If they choose to protect IP then they have to apply the provisions on non-discrimination.

What is parallel importation?

Paralell 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 is not considered as an infringement of the patent rights since the owner of IP is already awarded in the first market. However, TRIPS gives States flexibility to determine whether parallel importation is permissible in their jurisdictions or not.

What is voluntary licensing?

Voluntary licensing does not fall under the category of flexibilities. It is a business strategy of companies. It sometimes determines whether a compulsory licence should be issues or not.

What is the Medicines Patent Pool?

MPP is a UN-backed public health organisation and is an example of international voluntary licensing mechanism. “MPP partners with governments, industry, civil society, international organisations, patient groups and other stakeholders to forecast, prioritise and license needed medicines. The organisation encourages generic manufacture and the development of new formulations through patent pooling.”[32]

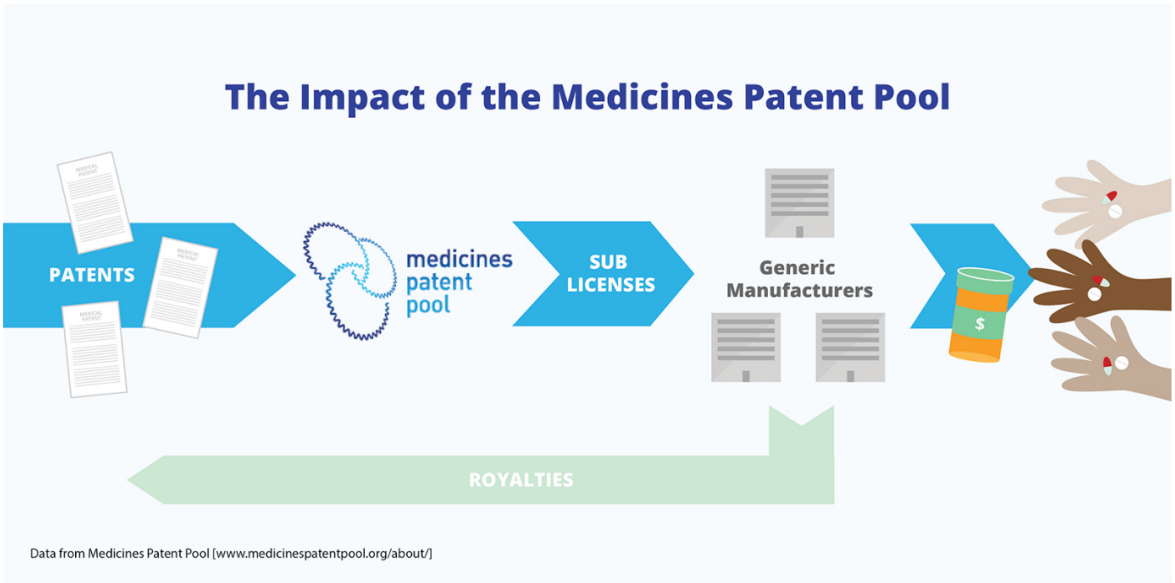

Figure 1.3 The impact of medicines Patent Pool (Source: Health Action International, 2016)

What type of exemptions are available for Less Developed Countries (LDC)?

Most African countries are members of the WTO, however, LDCs are exempted from applying some general provisions of the TRIPS until 2021 and medicines related provisions until 2023.

Most countries in various Regional Economic Communities (RECs) have revised or are in the process of revising their IP laws to incorporate TRIPS flexibilities. For example, within the SADC, Seychelles, Namibia and Botswana have started this process. Malawi and Zambia have draft laws, which purport to exclude pharmaceuticals from patentability until they graduate from LDC status.

What is the LDC waiver extension request?

This a request that was submitted by Bangladesh on 23 February 2016 on behalf of LDCs for an extension of the transitional period within which LDCs are exempted from protecting and enforcing pharmaceutical patents and test data under the TRIPS until 2033.

10. SOUTHERN AND EAST AFRICA USE OF FLEXIBILITIES

Which SEA countries have used flexibilities so far?

Of the 34 instances registered (by 2014) for compulsory licensing, 18 were from developing countries (DC) and only 3 were LDCs.[33] Of the SADC countries that have issued government use or compulsory licenses for generic ARVs, unfortunately only Zimbabwe produced quality generics at an affordable rate.

Country	Type	Year	Flexibility	Compound/Disease
Zimbabwe	DC	2002	CL	ARV, HIV/AIDS
Zimbabwe	DC	2003	GU	Local production ARVs, HIV/AIDS
South Africa*	DC	2003	CL	HIV/AIDS
Kenya*	DC	2004	CL	ARV, HIV/AIDS
Zambia	LDC	2004	CL	Local production of ARVs did not occur
Mozambique	LDC	2004	GU	Local production of ARVs
Gambia	LDC	2004	Paragraph 7	ARVs, HIV AIDS
Zambia	LDC	2004	Paragraph 7	ARVs, all medicines
Lesotho	LDC	2004	GU	ARVs, HIV/AIDS
Cameroon*	DC	2005	CL	NVP, 3TC
Chad	DC	2005	GU	ARV, HIV/AIDS
Angola	LDC	2005	Paragraph 7	All medicines
DRC	LDC	2005	Paragraph 7	ARVs, HIV/AIDS
Gabon	DC	2005	GU	ARV, HIV/AIDS
Ghana	DC	2005	GU	ARVs, HIV/AIDS
Rep of Congo	DC	2005	GU	HIV/AIDS
Mozambique	LDC	2005	GU	ARVs, HIV/AIDS
Swaziland	DC	2005	GU	ARVs, HIV/AIDS
Gabon	DC	2006	GU	HIV/AIDS
Senegal	LDC	2006	GU	ARVs, HIV/AIDS
Zambia	LDC	2006	Paragraph 7	ARVs, all medicines
Uganda	LDC	2006	Paragraph 7	ARVs, HIV/AIDS
Lesotho	LDC	2006	Paragraph 7	All medicines

Gambia	LDC	2007	Paragraph 7	All medicines
Rep of Congo	DC	2007	GU	ARVs, HIV/AIDS
Ivory Coast	DC	2007	CL	ARVs, HIV/AIDS
Rwanda	LDC	2007	Paragraph 7	All medicines
Rwanda	LDC	2007	Paragraph 6	Import of generic HIV/AIDS medicine from Canada.
Tanzania	LDC	2008	Paragraph 7	All medicines

*Compulsory licence not executed

Which SADC countries have TRIPS flexibilities in their national IP/patent laws?

Country	Type	Paralell import	Bolar	CL/GU
Angola	LDC	Unknown	No	Yes
Botswana	DC	Yes*	Yes	Yes***
DRC	LDC	Unknown	No	Yes***
Lesotho	LDC	Unknown	No	Yes***
Madagascar	LDC	Yes**	No	Yes***
Malawi	LDC	Unknown	No	Non-working or anticompetitive
Mauritius	DC	Yes*	No	Yes***
Mozambique	LDC	Yes**	No	Emergency, non-working
Namibia	DC	Yes*	Yes	Yes***
Seychelles	DC	Unknown	No	Yes***
South Africa	DC	Yes*	Yes	abuse, non-working, excessive price
Swaziland	DC	Unknown	No	Yes, public interest
Tanzania	LDC	Yes**	No	Only non-working, vital importance
Zambia	LDC	Unknown	In bill	Yes***
Zimbabwe	DC	Yes*	Yes	Yes***

*International version used, **National legislation used, ***Only non-working after 3 years

How has paragraph 6 system been used so far?

Rwanda is the only LDC that has successfully utilized the Paragraph 6 system to import drugs from a generic manufacture in Canada. The system was used to import TriAvir a fixed dose combination ARV from Apotex.

How have SADC member states incorporated TRIPS Flexibilities into their regional and domestic agenda?

The desire to address challenges related to access to medicines collectively led to the adoption of the SADC Pharmaceutical Business Plan (PBP) in 2006. The PBP was valid from 2007-2013. A new plan has since been developed and it covers the period 2015-2019. The overall goal of the plan is to "ensure the availability of essential medicines including African Traditional Medicines to reduce disease burden in the region."[34]

What does the East African Community Regional Pharmaceutical Manufacturing Plan of Action 2012-2016 entail?

The overall goal of the EAC Pharmaceutical Manufacturing Plan is to "ensure availability and access to affordable, high-quality and efficacious essential medicines for the treatment of priority communicable and non-communicable diseases in the region."[35] The plan's main objective is "to improve the capacity of the EAC region to sustainably and competitively produce quality essential medicines for local use and export."[36] The specific objectives of the plan include encouraging the "utilization of TRIPS flexibilities towards improved local production of pharmaceuticals."[37] The utilization of TRIPS flexibilities is thus seen as a tool for improving local production capacity in the region.

USEFUL RESOURCES

Websites:

http://makemedicinesaffordable.org/en/home/
http://accesstomedicines.org/

Videos:

Make Medicines Affordable - Evergreening Patents
https://www.youtube.com/watch?v=G9CGZFFI1ww

Articles and Books:

Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines. http://accesstomedicines.org/wp-content/uploads/private-patents-and-public-health.pdf
MSF Access to Essential Medicines Campaign: Untangling the web of antiretroviral price reductions, MSF, 2014: http://utw.msfaccess.org/

Access Challenges for HIV Treatment among People Living with HIV and Key Populations in Middle-Income Countries: Policy Brief, GNP+, NSWP, INPUD, MSMGF and ITPC, October 2013.
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