Regional Issue Brief:

INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES

For the Africa Regional Dialogue of the Global Commission on HIV and the Law

4 August 2011
Pretoria, South Africa
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Regional Issue Briefs and video of the Africa Regional Dialogue are available on the Commission’s website at www.hivlawcommission.org.

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**Africa Regional Advisory Group, Global Commission on HIV and the Law**

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<td>Researcher: Ghent &amp;Wits University</td>
<td>Marlise Richter</td>
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### Abbreviations

<table>
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<tr>
<th>Abbreviation</th>
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<td>AIDS</td>
<td>Acquired Immune Deficiency Syndrome</td>
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<td>ARIPO</td>
<td>African Regional Intellectual Property Organisation</td>
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<td>ART</td>
<td>Anti-retroviral Therapy</td>
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<td>DRC</td>
<td>Democratic Republic of Congo</td>
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<td>EAC</td>
<td>East African Community</td>
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<td>EPA</td>
<td>Economic Partnership Agreement</td>
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<td>FTA</td>
<td>Free Trade Agreement</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>LDC</td>
<td>Least Developed Country</td>
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<tr>
<td>TAC</td>
<td>Treatment Action Campaign</td>
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<td>TRIPS</td>
<td>Trade-Related Aspects of Intellectual Property Rights</td>
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<td>UN</td>
<td>United Nations</td>
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<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV and AIDS</td>
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<td>UNDP</td>
<td>United Nations Development Programme</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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<td>WTO</td>
<td>World Trade Organisation</td>
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Executive summary

The global focus on the HIV and AIDS pandemic and, in particular, on sub-Saharan Africa has concentrated the minds of policy-makers, governments and civil society on the issue of access to medicines by the world’s poor, and to the multiple impediments to achieving access.

Collapsing health systems, poor health infrastructure, extreme poverty, a huge disease burden, the lack of availability of and the poor quality of drugs, inordinately high prices of medicines, and the trade rules and intellectual property protection inherent in them, all contribute to the lack of access to medicines which are safe, effective and affordable.

With the advent of the World Trade Organisation (WTO), and the adoption of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, member countries were required to harmonise their patent legislation and submit to stringent standards for the protection of patents on, \textit{inter alia}, medicines and medical devices. Some African countries have done so, while others are yet to align their intellectual property legislation to the new international regime.

This briefing paper reviews the extent of patent protection on pharmaceuticals in African countries, the incorporation of so-called ‘flexibilities’ into their domestic legislation, and makes some preliminary comments on the prospects for access-friendly legislation in many of these countries.\textsuperscript{56}

\textsuperscript{56} The term ‘flexibility’ is used to denote measures or mechanisms contained in international and domestic intellectual property laws, which may be used to limit the rights of the IP holder, in order to increase access to particular goods. They include compulsory licences, parallel importation, exceptions and exclusions from patentability, stringent patent standards, and the waiver delaying recognition of patents on medicines.
According to the 2010 UNAIDS Report on the Global AIDS Epidemic, African countries accounted for some 23 million of the 33.3 million global HIV infections, with the figure for sub-Saharan Africa alone standing at a staggering 22.5 million.\(^\text{57}\)

One of the success stories of the global response to this crisis is the fact that around 6.6 million people were receiving anti-retroviral therapy (ART) in low- and middle-income countries at the end of 2010, a nearly 22-fold increase since 2001.\(^\text{58}\) This has been made possible by the availability of affordable quality generics medicines, increases in donor funding, investments in health systems, and the use of flexibilities available in intellectual property laws.\(^\text{59}\)

However, the demand for treatment far exceeds the targets reached, with the ‘treatment gap’ currently standing around ten million.\(^\text{60}\) As a result, the recent UN General Assembly High Level Meeting in June 2011 was forced to adopt some bold targets: among others, to eliminating new HIV infections among children in the next five years, increasing the number of people on life saving treatment to 15 million, and reducing tuberculosis-related deaths in people living with HIV by half, in the same time period.\(^\text{61}\)

The success of the roll out of first-line ART was largely due to the ability of generic manufacturers to supply cheaply. Since India, a major supplier of generic pharmaceuticals had to comply with the TRIPS requirements to provide product patent protection on medicines in 2005, the landscape has changed significantly. A critical factor in the affordability of newer, second- and third-line antiretroviral medicines is the impact of patent protection. Thus developing countries will need to increasingly utilise the flexibilities available under intellectual property rules, in order to avoid, or mitigate the negative effect of expected high monopoly prices attaching to newer medicines.

This paper examines the readiness of African countries to avail of such flexibilities. It does so by:

- Reviewing the patent legislation in select countries
- Analysing the common threads in their intellectual property regimes
- Examining the extent to which permissible flexibilities have been incorporated into their domestic law
- Exploring the impact of regional intellectual property rights agreements and free trade agreements (FTAs) on access to medicines
- Making some recommendations for better positioning themselves to meet the challenges.

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\(^{60}\) Ibid.

Most African countries have incorporated intellectual property protection in their domestic laws, including the granting of patent protection on medicines. There are now 53 countries on the African continent, of which 42 are members of the WTO and liable to comply with its rules, notably the TRIPS Agreement. At least half of this number consists of the least developed countries, who are eligible to apply the WTO waiver regarding providing patent protection to pharmaceuticals. Regrettably, countries have not taken advantage of this important flexibility. This paper undertakes a snapshot survey of some 46 countries, and a more annotated review of selected countries, on the basis of available information.

The situation persisting in individual countries is as follows.

**Angola**

Intellectual property legislation pre-dates TRIPS. The patent office carries out a substantive examination of patent applications. It provides for the issuance of compulsory licences on the grounds of failure to work, failure to meet demand and on grounds of public interest, national security, public health, and in the interests of the economy. No exceptions or other flexibilities are provided for.

**Botswana**

Intellectual property matters are governed by post-TRIPS legislation. Patent applications are examined by virtue of Botswana’s membership of the African Regional Intellectual Property Organisation (ARIPO). Provision is made to issue compulsory licences on account of failure to supply the domestic market on reasonable terms, and for government use orders. There are no provisions for parallel importation, or for an early working exception, but experimental or scientific exceptions are permitted.

**Democratic Republic of the Congo (DRC)**

Legislation pre-dates TRIPS. It makes provision for granting compulsory licences for failure to work and to supply the domestic market. New and second uses are not patentable.

**Egypt**

Egyptian patent law is TRIPS-compliant, and includes provisions for compulsory licences on various, including public health grounds and anti-competitive licences; parallel importation; early working and research exceptions. The government has further promulgated Law No 82/2002 to apply some of the following ‘flexibilities’: the establishment of a fund ‘to ensure the stability of medication prices, and the issuance of a compulsory licence if the patent relates to ‘life-giving medication or chronic diseases.

**Ghana**

Patent legislation is TRIPS-compliant. Compulsory licences may be granted in the case of anti-competitive practices, for refusal to licence, failure to exploit, and in the case of emergency. Provision is also made for government use orders. Ghana has adopted an international exhaustion regime, permitting parallel importation. Experimental and scientific use exceptions are permitted, but there is no early working exception.
Kenya
Kenya’s intellectual property legislation became TRIPS-compliant in 2002. Patent protection is available through national filing, with a developed system of examination of applications. The law contains some key flexibilities, for example, compulsory licences for failure to exploit or to meet demand, government use orders for public interest and anti-competitive purposes, and early working and research exceptions. Additionally, Kenya has one of the most liberal applications of the international exhaustion principle, permitting parallel importation of both branded and legitimately-marketed generic medicines. In addition Kenya has also adopted anti-counterfeiting legislation, widely regarded as TRIP-plus enforcement measures which militate against access to medicines.

Lesotho
The pre-TRIPS legislation makes provision for the issuance of compulsory licences for failure to work locally, in the public interest and national security; research exceptions, but not for early working, and the exhaustion principle has only national application.

Madagascar
The intellectual property regime is governed by pre-TRIPS legislation, which entails both formal and substantive examination of patent applications. Compulsory licenses may be awarded for a variety of reasons, including failure to work or insufficient working, refusal to license on reasonable terms, or failure to meet domestic demand. Exceptions include acts done for non-commercial or industrial purposes, such as early working and experimental use.

Malawi
Patent protection is provided under pre-TRIPS legislation, although as a least developed country (LDC), Malawi is not obliged to provide patent protection on pharmaceuticals until 2016. There are no provisions for exceptions, and only limited compulsory licences for failure to exploit, or because of unmet demand. There are no provisions for parallel importation. However, the legislation makes provision for extension of a patent term by five to ten years, in addition to the initial grant of 16 years.

Mozambique
Legislation is TRIPS-compliant. Compulsory licences may be granted in cases of emergency, failure to exploit, failure to meet demand, refusal to license or anti-competitive conduct. There is neither provision for international exhaustion, nor for an early working exception, but non-commercial and scientific uses are permitted.

Namibia
The applicable statute is the old South African legislation, of which the patent and design provisions remain in force. Compulsory licences may be granted for failure to work or refusal to license. An international exhaustion regime applies, permitting parallel importation. An early working exception is allowed, but there is no research exception. There is a mere formal registration of patents, with no substantive examination. Currently, there is draft legislation to revise the outdated statute, and to make the intellectual property regime TRIPS-compliant.

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Nigeria

Legislation pre-dates TRIPS. Compulsory licences may be granted for failure to work or meet demand, and on public health, national security and environmental grounds. Government use orders are also available. Parallel importation is not permitted. However, an early working exception is available, as is research, teaching, and private and non-commercial use.

Rwanda

Legislation pre-dates TRIPS. There is no provision for a compulsory licence, but a patent may be revoked for failure to work within four years of grant. However, Rwanda appears to have used its status as a least developed country to access medicines from a Canadian manufacturer who obtained an export compulsory licence under that country’s Access to Medicines Regime, in line with the WTO Paragraph 6 Decision.

South Africa

South Africa has a well-developed legal and regulatory framework. The Patents Act has been amended to become TRIPS-compliant, extending the patent term to 20 years (from a previous 16). The legislation contains provisions for the grant of compulsory licences in limited circumstances (non-working, failure to meet demand, refusal to license), government use, and revocation under certain circumstances. Recent amendments have introduced provisions for an early working exception, and the principle of international exhaustion permitting parallel importation.

This legal framework does not fully take advantage of all possible flexibilities under TRIPS and the Doha Declaration. In particular, it does not include all available public health grounds for the issuance of compulsory licences, research and educational exceptions, provisions for pre- and post-grant opposition of patent applications, contains a limited ambit for revocation of patents, and signal, does not conduct substantive examination of patent applications.

South Africa has had some successes in improving access to medicines through the utilisation of its competition law framework. Thus, as a result largely of the efforts of civil society and patient groups, the first series of voluntary licences were issued for ART in 2003, as a result of a complaint to the Competition Commission.

Swaziland

Legislation is TRIPS-compliant. Compulsory licences are available on grounds of public interest, health, security and nutrition. There is no early working exception, and patent rights extend only to acts done for industrial or commercial purposes.

Tanzania

Legislation pre-dates TRIPS. Compulsory licences may be granted on grounds of failure to work or meet demand, public health or defense, or refusal to license. There is no provision for parallel importation, nor for early working, but scientific research use is permitted.

Uganda

The applicable law pre-dates TRIPS but makes provision for some limited grounds for the grant of compulsory licences (failure to work, failure to meet demand; refusal to license, or as a result of anti-competitive practices), and also government use orders. Parallel importation is constrained by the national exhaustion principle, and while there is no provision for an early working exception, research and experimental uses are permitted. As in Kenya,
anti-counterfeiting legislation, which can potentially block access to legitimate generics, is under consideration.

Zambia

The applicable legislation is TRIPS-compliant.\(^89\) It includes provisions for the issuance of compulsory licences for failure to work, failure to meet demand, a refusal to license, and for anti-competitive behaviour, as well as for government use orders. There is no early working exception, but provision is made for a scientific research exception. No parallel importation provision is available.

Zimbabwe

Zimbabwe’s legislation is TRIPS-compliant.\(^90\) It includes some of the TRIPS flexibilities, for example, compulsory licences for the abuse or insufficient use of patent rights, failure to meet demand, refusal to license, and on account of anti-competitive practices. The government declared a public health emergency in 2002, and a compulsory licence was granted to a local company to import and produce ART.\(^91\) The declaration also provides for parallel importation of generic HIV-related drugs. Other provisions in the law include an early working exception.

\(^89\) Industrial Property Act of 2001, Zambia.
Analysis of common features in Intellectual property laws

The key features of intellectual property legislation in African countries are included in a table (Appendix A).92

Patent examination

The majority of countries do not have a system of substantive patent examination, there being a mere registration process of approving the formalities for applications. The exceptions, where substantive examinations of application take place are Angola, the DRC, Egypt, Kenya and Madagascar. Other countries have their patent applications examined by regional bodies such as ARIPo (Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe)93 or the Organisation Africaine de la Propriété Intellectuelle (OAPI) i.e. Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Republic of Congo, Cote d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Togo.94

Patents on new forms and uses of medicines

Only 2 countries (the DRC and Malawi) appear to have express provisions excluding such patents. Some, such as South Africa, have strict patent standards on paper, which would appear to exclude new forms and uses, but as no substantive examination is conducted by the patent office, such standards are not maintained. However, case law suggests that new forms of medicines are patentable.95 Many countries do not exclude such types of patents, by virtue of their membership of ARIPo or OAPI.

Compulsory licences

This is a flexibility available in virtually every system surveyed, the common grounds for the grant of which are failure to work, failure to meet demand, or to supply the domestic market on reasonable terms. Many countries have additionally included refusal to license, as well as a range of grounds relating to public health and interest, nutrition, national security and the environment. A small number also grant compulsory licences for anti-competitive practices. None of the countries have fully incorporated the public health grounds as clarified by the Doha Declaration, and only Rwanda has utilised the Paragraph 6 Decision for import of limited quantities of medicines under the WTO’s notification system.96

Parallel importation

This is yet another flexibility that has not been widely adopted by African countries, despite the clarification provided in the Doha Declaration. Of the countries surveyed, only eight have adopted the principle of international exhaustion, permitting parallel importation from anywhere in the world. Kenya’s provisions, go much further, and permit importation of both branded and legitimately produced generic medicines.

Exceptions

Only nine countries appear to have provisions for early working. A larger number of countries provide for educational, research or experimental use exceptions. This is yet another area where countries have not adopted all available flexibilities in order to enhance access to medicines.

Opposition procedures

Not a single country surveyed made provision for pre- or post-grant opposition to patent applications. This is

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92 This table draws heavily on previously published work by Musungu & Oh (2006) and Musungu (2007), and these contributions are gratefully acknowledged.
94 For information on OAPI, see Lawyers for Africa. Available at: http://www.lawyersforafrica.com/oapi.htm [Accessed on: 17 May 2012].
hardly surprising as many do not have the capacity to conduct substantive examinations. No opposition procedure is available under regional examination systems such as ARIPO and OAPI.97

Test data exclusivity

Only two of the countries surveyed, namely Egypt and Mauritius, provided express test data exclusivity measures. In the majority of instances, there are no specific provisions in this regard. In all those cases, countries will have to provide for ‘protection’98 of data, as opposed to the more onerous ‘exclusivity’ provisions, which disallow drug regulators from referencing the data of innovator companies, when considering an application for a generic equivalent.

“Anti-counterfeiting” legislation

The East African Community (EAC) and a number of countries have either adopted, or are the process of adopting legislation purportedly to regulate the serious problem of substandard and falsified medicines. The main criticism leveled against these measures is that they conflate quality and safety issues (the responsibility of drug regulators) with intellectual property enforcement (that of private law enforcement). ‘Counterfeit,’ in these laws, has come to be so widely defined as to attack legitimate generics.99 The issue is discussed in the section on TRIPS-plus initiatives.

98 As provided in Article 39 of the TRIPS Agreement. Available at: http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm [Accessed on: 17 May 2012].
The role of regional agreements in intellectual property protection in Africa

Only a small group of countries (Algeria, Egypt, Ethiopia, Kenya, Morocco, Mozambique and Zambia) have local patent offices with the capacity to examine patent applications at a national level. A larger group of countries rely on patent examiners at ARIPO and the francophone OAPI to determine whether a patent application fulfils the three requirements for patentability. It is important to note that participation in a regional patent organisation may lead to a reduction in policy space for member states in making use of the flexibilities, or, as discussed below, hinder the integration of the TRIPS public health flexibilities at national levels, or even make it impossible.

The Bangui Agreement and the African Intellectual Property Organisation (OAPI)

The Bangui Agreement is an international law instrument that governs intellectual property matters in all the sixteen member states of OAPI, which are Benin, Burkina Faso, Cameroon, Central African Republic, Congo, the Ivory Coast, Gabon, Guinea, Guinea Bissau, Equatorial Guinea, Mali, Mauritania, Niger, Senegal, Chad, and Togo. The Bangui Agreement was signed in 1962, before the emerging of the WTO and the TRIPS Agreement. The Bangui Agreement was revised in 1999, when the TRIPS Agreement was already in place; however, the public health flexibilities included in the TRIPS Agreement were not incorporated in the revisions. The Bangui Agreement favours strong intellectual property protection and does not include many of the TRIPS flexibilities such as stricter patentability criteria, exceptions and exemptions, compulsory licenses and government use orders (as formulated by the TRIPS Agreement) and others. The Bangui Agreement also does not take into account the development status of the member states, in particular the waiver of the obligations of LDCs under the TRIPS Agreement from providing patents to pharmaceuticals until 2016. OAPI, headquartered in Yaoundé, Cameroon, does not carry out substantive patent examination prior to granting a patent – unlike ARIPO, which is discussed further. Also in contrast to ARIPO, which allows its Member States the opportunity to accept or to reject a pharmaceutical patent, once a patent is granted by the OAPI Secretariat, it becomes directly applicable in all sixteen Member States.

In order to enable OAPI Member States, who are also parts of the WTO to incorporate the TRIPS Agreement flexibilities in their national laws, there is a need to reform the Bangui Agreement. In 2009, UNDP, in partnership with the Association for the Promotion of Intellectual Property in Africa (APPiA), the Regional Office for Central Africa of the World Health Organisation (WHO - AFRO) and the non-governmental organisation Third World Network (TWN) called a regional consultation on the need to reform the Bangui Agreement. The comprehensive analysis of the provisions from a public health perspective and the recommendations of the participants in the consultation were submitted to OAPI leadership.

The African Regional Intellectual Property Organisation (ARIPO)

ARIPO was established in with the Lusaka Agreement, adopted by a diplomatic conference held in Zambia, on 9 December 1976. The Lusaka Agreement also pre-dates TRIPS and the WTO. Provisions on patents are contained in the “Protocol on Patent and Industrial Designs within the Framework of ARIPO”, known as the “Harare Protocol”, signed in Zimbabwe in 1982. The following countries are Member States of ARIPO: Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. Member States rely on the organisation to determine whether a patent application fulfils the three requirements for patentability. The ARIPO patent examiners conduct the examination for Member States, and, in some instances, the 13 observer countries. Each Member State has a six-month period from the granting of a patent by an ARIPO patent examiner to confirm or reject the application of the patent in its territory.

100 In addition to the 16 Member States, there are 14 observer countries, which are regarded as potential ARIPO members. These are Angola, Algeria, Burundi, Egypt, Eritrea, Ethiopia, Liberia, Libya, Mauritius, Nigeria, Seychelles, South Africa and Tunisia. See ARIPO. Available at: http://www.aripo.org/ (Accessed on: 17 May 2012).
Use of compulsory licences in African countries

To date, five countries have availed themselves of their laws to issue compulsory licences for medicines, with varying success. In 2002, Zimbabwe published a declaration of a state of emergency for HIV and AIDS for six months (later extended for further terms), enabling the government or an authorised person to “make or use any patented drug, including any antiretroviral drug” and “to import any generic drug used in the treatment … of HIV/AIDS.” This was followed by Mozambique in 2004, wherein a compulsory licence was issued to the company Pharco, for the supply of the triple compound combination of lamivudine, stavudine and nevirapine, with royalty payment to the patent owners not to exceed 2%. Also in 2004, The Zambian government issued a licence, also to Pharco, for the same combination, at a royalty rate not exceeding 2.5%. Compulsory licenses were issued by Eritrea and Ghana as well, in 2005. The compulsory licenses and government use orders issued by African countries are summarised in the table below:

<table>
<thead>
<tr>
<th>Country and date</th>
<th>Type of license and generic name of medicine</th>
<th>Duration of license</th>
<th>Remuneration</th>
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<tbody>
<tr>
<td>Ghana October 2005</td>
<td>Ministry of Health declared emergency situation. Compulsory license for import of generic ART for non-commercial use</td>
<td>Until the emergency situation lasts</td>
<td>Not in compulsory licence</td>
</tr>
<tr>
<td>Eritrea June 2005</td>
<td>Ministry of Health declared emergency situation. Compulsory license for import of generic ART for non-commercial use</td>
<td>Until the emergency situation lasts</td>
<td>Not in compulsory licence</td>
</tr>
<tr>
<td>Zambia September 2004</td>
<td>Compulsory license to a local generic producer for a two types of triple combination fixed dose ART (one is lamivudine/stavudine/nevirapine)</td>
<td>Until situation changes</td>
<td>≤ 2.5% of total turnover of products at the end of each fiscal year</td>
</tr>
<tr>
<td>Mozambique April 2004</td>
<td>Compulsory license to a local generic producer for two types of triple combination ART</td>
<td>Until situation changes (triple combination was not being sold on the Mozambique market)</td>
<td>≤ 2% of total turnover of products at the end of each fiscal year</td>
</tr>
<tr>
<td>Zimbabwe May 2002</td>
<td>Minister of Justice declared emergency situation. Compulsory license for seven first-line ARV to a local generic producer</td>
<td>Initially six months, then emergency extended until 31 December 2008</td>
<td>Not in compulsory licence</td>
</tr>
</tbody>
</table>

Use of the WTO August 30 Mechanism by Rwanda and Canada

Nearly four years after the adoption of the WTO Mechanism for compulsory licenses for export to countries which insufficient or no manufacturing capacities (the 30 August Decision), Rwanda became the first WTO Member State to use it. On 17 July 2007, Rwanda notified the WTO of its intent to import from Canada 260,000 packs of Apo-TriAvir, a generic version of a triple fixed dose ART combination patented by GlaxoSmithKline, Shire and Boehringer Ingelheim. As an LDC, Rwanda did not have to demonstrate that it did not possess domestic manufacturing capacity, as specified by the Mechanism.

From the Canadian side, Rwanda’s notification was matched by Canada’s issuance of a compulsory license for export in September 2007 upon application from Canadian generic manufacturer Apotex. The license was issued under Canada’s legislation to implement the 30 August Decision allowing domestic companies to produce generic products under patent protection for export.

103 Compulsory Licence No CL 01/2004, Republic of Zambia.
Canada notified the WTO on 4 October 4 2007, stating that its patent authorities had issued a compulsory license to national generic company Apotex, to legally make 15.6 million tablets of Apo-TriAvir for export to Rwanda over the next two years. The notification also provided the link to a new website of Apotex which described the product as required by the 30 August Decision.

It took almost another year before the products were finally shipped off to Rwanda in September 2008. While the case has been praised in terms of providing Rwanda with essential medicines, the time and effort to make it happen have been criticised, highlighting the complex nature of the mechanism and government procurement rules and practices.  

**Use of competition provisions in South Africa**

Article 31(k) of the TRIPS Agreement allows the use of a patent without the consent of the patent holder “to remedy a practice determined … to be anti-competitive.” Under Article 31 (k) no prior negotiations with patent holder are required and the compulsory license is not required to serve predominantly the domestic market. Correcting anti-competitive practices may be taken into account when the amount of remuneration case of licenses under Article 31(k). Competent authorities shall have the authority to refuse termination of authorisation if and when the conditions that led to such authorisation are likely to recur. While no compulsory license was issued, South Africa has relied twice on competition law provisions to address excessive pricing of medicines and in both cases has achieved substantial reductions. In 2002, a civil society coalition filed a complaint against GlaxoSmithKline and Boehringer Ingelheim before the South African Competition Commission, arguing that these companies were engaging in anticompetitive practices through excessive pricing of their patented anti-retrovirals (zidovudine, lamivudine, and nevirapine). The complainants maintained that even after taking into account costs of research and development, production, shipment, and profit, the prices that the companies were charging were excessive and unjustifiable.

South Africa’s Competition Commission agreed with the complainants, and found that the companies had engaged in excessive pricing, and in addition had denied generic competitors with an “essential facility” (in this case, licenses to manufacture these medicines). The Commission recommended to South Africa’s Competition Tribunal that a compulsory license be issued on the patents covering these anti-retrovirals, along with punitive measures. Before the matter could be heard by the Competition Tribunal, considering the possible effect of the Competition Commission’s findings, the companies agreed to grant voluntarily licenses for their patents to generic producers at a royalty not in excess of 5% of the sale price of the generic versions.

In 2007, the Treatment Action Campaign (TAC) brought a complaint against the multinational pharmaceutical manufacturer Merck Sharp & Dohme for refusing to license its patent on the anti-retroviral efavirenz on reasonable terms. Before the matter could be referred to the Competition Tribunal, MSD and TAC reached a settlement whereby Merck Sharp & Dohme agreed to grant multiple licenses on its efavirenz patent to generic producers, for supply of both the public and private sectors. Further, Merck Sharp & Dohme agreed to allow the generic producers to export their products to ten other African countries, and waived any right to a royalty.

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The effect of trade agreements on Intellectual property rights and access to medicines

As part of its Global Europe strategy, the European Union (EU) has been in negotiations during the past five years, with, among others, various African blocs of countries such as the Southern African Development Community (SADC), ESA (East and Southern Africa), ECOWAS (West Africa) and CEMAC (Central Africa). With some country exceptions, these blocs have all signed interim Economic Partnership Agreements (EPAs) with the EU in respect of trade in goods. None of these interim agreements have substantive provisions on intellectual property, but countries have committed to future negotiations on these matters. The significance of these negotiations is that countries still have an opportunity not to commit to stronger intellectual property protections in these EPAs than is required by TRIPS. Typical TRIPS-plus measures included in FTAs with high-income countries are:

• Broadening patentability, for instance by introducing patenting of new forms and/or new uses of known substances, thereby enabling the "evergreening" of medicines. Often FTAs with intellectual property provisions require the patentability of therapeutic and surgical methods, the exclusion of which is allowed by the TRIPS Agreement.

• Extending patent duration beyond the 20 years required by TRIPS, allegedly to compensate for delays in granting the patent, while in fact prolonging the patent monopoly and further restraining the entrance of generic competitors to the markets.

• Restricting patent oppositions, which have proven successful in some countries around the world to prevent questionable patents on essential medicines from being granted.

• Introducing test data exclusivity. Although Article 39.3 of the TRIPS Agreement does not require test data exclusivity, but "protection of undisclosed data from unfair commercial use", high-income countries are pressuring developing countries to adopt and implement such measures. Test data exclusivity prevents the registration and consequently the use of generic equivalents in the country for the duration of the exclusivity period, even if the medicine is not patented.

• Introducing patent-registration linkage that prevents the approval/registration of new medicines by national drug regulatory authorities if it could potentially infringe existing patents.

TRIPS-plus initiatives in intellectual property enforcement and their likely impact on access to medicines

In certain countries in Sub-Saharan Africa there has been a strong emphasis on intellectual property enforcement measures and the development of “anti-counterfeiting” legislation as a way to curtail trade in substandard and falsified medicines. The concern is legitimate, as the region faces serious challenges around the availability of safe and efficacious medicines of good quality at affordable prices. Manufacturing and smuggling of substandard and falsified medicines is an organised criminal activity that brings large revenues.\(^{107}\)

The “anti-counterfeiting” approach purports to address the problem of quality, safety and efficacy of medicines by enforcing intellectual property rights. In fact, while there is no proof that intellectual property rights enforcement has led to a decrease in the supply of substandard and spurious medicines, there already is evidence to suggest that it has hampered access to generic medicines, including ART. Since 2008, at least 17 seizures of legitimate generic medicines transiting European borders and destined to the developing world were carried out by customs officials under the pretext that the medicines were “counterfeit”. At least one seizure was of ART – in this case, a legitimate UNITAID/Clinton Foundation shipment to Nigeria.\(^{108}\)

There is lack of consensus on the meaning of the term “counterfeit medicines”, as various sources provide different interpretations. For instance, a broad interpretation of Kenya’s Anti-counterfeit Act of 2008 included generic medicines under the definition of a “counterfeit”. The law was challenged at Kenya’s Constitutional Court by individuals living with HIV as impinging on the constitutional right to health. In April 2010, a Constitutional Court justice issued a conservatory order on the application of the law to medicines until a verdict is delivered.\(^{109}\) In Uganda, a draft Counterfeit Goods Bill has been discussed since 2008 and after the Kenya court decision its definition has been amended but the Bill is still being discussed. Zambia and Malawi are also in the process of adopting “anti-counterfeiting” laws, and Tanzania adopted such legislation in 2008. Anti-counterfeiting legislation is discussed at EAC level as well, and, if adopted, it will require all EAC Member States to introduce “anti-counterfeit” measures and will prevail over any contradicting national provisions.

The “anti-counterfeiting” approach has been criticised as conflating legitimate concerns of quality, safety, and efficacy with intellectual property compliance. There is no evidence that “anti-counterfeiting laws” effectively prevent the spread of substandard and falsified medicines, while there is growing evidence that such measures could hamper access to generics. “Anti-counterfeiting” laws do not address public health threat posed, for instance, by defective or inappropriately stored medicines where no IP rights have been infringed. Furthermore, they envision TRIPS-plus enforcement measures such as injunctions, seizures, destruction, and other, under the presumption that the complainant’s claim has merit and typically without sufficient safeguards against abuse. These factors can be major disincentives for generic manufacturers to enter markets where “anti-counterfeiting” measures exist, and yet such measures are unlikely to stop criminal producers and smugglers of substandard and falsified drugs. This is the reason why access to medicines and treatment advocates suggest developing a “positive agenda” focused on enhancing the capacity of drug regulatory authorities, training of personnel and investing in quality control facilities rather than earmarking substantial public funds for the protection of private proprietary interests.\(^{110}\)

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A major drawback in conducting this review is the availability of up-to-date information on the status of intellectual property legislation in various African countries. What emerges is a diverse range of legal frameworks, many of them dating back to the colonial era, and still out of step with recent developments in international norms and rules. The so-called ‘modernisation’ of their laws is at once also an opportunity to align them with the developmental objectives of these societies. Thus, new legislation must not only aim to be TRIPS-compliant, but also endeavor to incorporate all progressive measures which will contribute to the social, economic and industrial advancement of developing countries.

In the context of intellectual property legislation as it impacts on access to medicines, it will mean:

• Utilising the waiver available to least developing countries, of which there are several in Africa, to exempt medicines from patent protection. This will enable poor countries to source essential medicines cheaply without the strictures of patent protection, until at least 2016, and possibly later.

• Where countries are required to comply with TRIPS, in the first instance, they ought to set their patenting standards at the highest possible level (using the freedom given them in terms of Article 1.1 of TRIPS), in order to grant patents on genuine innovations only, thereby preventing the practice of ‘evergreening’ which through the extension of patent protection, prevents generic competitors from entering the market.

• In the second instance, patent applications ought to be subjected to strict examination to satisfy the criteria for their grant, and governments must consider investment in domestic and/or regional institutions capable of upholding strict patenting standards.

• Third, the grounds for the grant of compulsory licences need to be widened considerably in order to take advantage of all available flexibilities. These include:
  • Public health licences, not limited to specific diseases, quantities or time frames.
  • Licences for excessive pricing which limits access to medicines.
  • Express licences for anti-competitive conduct by a patent holder.
  • Import licences (for non-producer countries) under the WTO Paragraph 6 Decision.
  • Setting low royalty rates for licences granted for public health purposes.

• Fourth, expanding the scope of medicines that may be covered by parallel importation, to include legitimately produced generics.

• Fifth, the introduction of opposition procedures, both before and after the grant of a patent, so that the patent examiner is afforded the opportunity to consider all relevant factors, including evidence of prior art, existence of inventive step, and other essential criteria.

• Sixth, making fullest use of all available exceptions permitted under the law, to include the early working exception, as well as exceptions for educational, research, experimental, private and non-commercial use.

• Seventh, to use the language of Article 39 of the TRIPS agreement to protect data (as required) but to expressly exclude data exclusivity over clinical trial and other data in relation to medicines.

• Eighth, to resist provisions in FTAs and economic partnership agreements which demand data exclusivity, patent term extensions, linkage between patent status and the registration of generic versions, and strong enforcement rules such as anti-counterfeiting laws and border control measures, which abuse scarce state resources for the protection private property rights.

Such measures, if adopted, will better align the intellectual property laws of African countries to their development goals, and go a long way towards enhancing access to medicines for their populations. It does, of course, require resources, technical capacity and, most important, political will on the part of African leadership and communities to achieve this.
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OAPI http://www.lawyersforafrica.com/oapi.htm


Pfizer & Ano v Cipla Medpro & Ors 2005 BIP 1.


This table draws heavily on previously published work by Musungu & Oh (2006) and Musungu (2007), and these contributions are gratefully acknowledged.

<table>
<thead>
<tr>
<th>Country</th>
<th>Date of WTO Membership</th>
<th>DC / LDC</th>
<th>Patent Law / Examination Etc.</th>
<th>Comp Law / Opposition</th>
<th>Data Prot. / Parallel Imports</th>
<th>Enforcement Issues</th>
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</table>

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<tr>
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<th>Opposition</th>
<th>Data Prot</th>
<th>Comp Law</th>
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<td>Intellectual Property Law 82, 2002. Has system of patent examination, taking +/- 3 yrs</td>
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<td>Limited examination through OAPI</td>
<td>Not excluded</td>
<td>Failure to work; unmet demand; public health; national security; environment; dependents; after 4 years; also G. use.</td>
<td>National</td>
<td>Yes, early working; research; private &amp; non-commercial use; teaching.</td>
<td>Yes</td>
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<td>Nigeria 1 Jan 1995</td>
<td>DC</td>
<td>The Patent and Designs Act, 1971; Draft Bill of 1990</td>
<td>Allowed in draft bill</td>
<td>Failure to work; unmet demand; public health; national security; environment; dependents; after 4 years; also G. use.</td>
<td>National</td>
<td>Yes, early working; research; private &amp; non-commercial use; teaching.</td>
<td>Yes</td>
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<tr>
<td>COUNTRY (date of WTO membership)</td>
<td>DC / LDC</td>
<td>Patent law; Examination Etc.</td>
<td>New / 2nd Use Allowed</td>
<td>Compulsory Licences</td>
<td>Parallel Import</td>
<td>Exceptions</td>
<td>Opposition</td>
<td>Data Prot</td>
<td>Comp Law</td>
<td>Enforcement Issues</td>
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<td>Rwanda 22 May 1996</td>
<td>LDC</td>
<td>Patents Act of 1963. Only formal examination.</td>
<td>Not excluded</td>
<td>Failure to work within 4 years — ground for revocation.</td>
<td></td>
<td></td>
<td></td>
<td>No specific provision</td>
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<td>Senegal 1 Jan 1995</td>
<td>LDC</td>
<td>Limited examination through OAPl.</td>
<td></td>
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<td></td>
<td>No specific provision</td>
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<td>Sierra Leone 23 July 1995</td>
<td>LDC</td>
<td>Only formal examination.</td>
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<td></td>
<td></td>
<td>No specific provision</td>
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<td>South Africa 1 Jan 1995</td>
<td>DC</td>
<td>Patents Act 1978. Examination as to formalities only.</td>
<td>No, but no examination to verify</td>
<td>Dependants, abuse of patent (non-working; failure to supply the domestic market; refusal to license; excessive pricing; also Govt use)</td>
<td>International</td>
<td>Yes, early working; no research or educational</td>
<td>No.</td>
<td>No specific provision</td>
<td>Yes, Anti-comp practice prohibited</td>
<td></td>
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<tr>
<td>Sudan</td>
<td>LDC</td>
<td>Patent Act, 1971</td>
<td>Not excluded</td>
<td>Non-working; defence; public health Govt use</td>
<td>National</td>
<td>None</td>
<td>No specific provision</td>
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<tr>
<td>Swaziland 1 Jan 1995</td>
<td>DC</td>
<td>Patents, Utility Models and Industrial Designs Act No 6 of 1997 Only formal examination.</td>
<td>Not excluded</td>
<td>Govt. use; public interest, health security; nutrition</td>
<td>No early working, but patents only for industrial/commercial purposes</td>
<td>No early working, but scientific research</td>
<td>No specific provision</td>
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<td>Tanzania 1 Jan 1995</td>
<td>LDC</td>
<td>Patents Act, 1987. Only formal examination, but may be substantive in certain fields.</td>
<td>Not excluded</td>
<td>Failure to work; unmet demand; public health or defence; refusal to license; dependents; after 4 years, also G. use</td>
<td>National</td>
<td>No early working, but scientific research</td>
<td>No specific provision</td>
<td>Anti-counterfeiting legislation.</td>
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<td>Togo 31 May 1995</td>
<td>LDC</td>
<td>Limited examination through OAPl.</td>
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<td></td>
<td></td>
<td></td>
<td>No specific provision</td>
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<tr>
<td>COUNTRY</td>
<td>DC / LDC</td>
<td>Patent law; Examination Etc.</td>
<td>New / 2nd Use Allowed</td>
<td>Compulsory Licences</td>
<td>Parallel Import</td>
<td>Exceptions</td>
<td>Opposition</td>
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<td>Tunisia</td>
<td>DC</td>
<td>Law No 2000-84 on Patents. Only formal examination.</td>
<td>Failure to work; unmet demand, after 3 years of filing; also G. use</td>
<td>Inter-national</td>
<td>Yes, early working for generics; private, non commercial, experimental</td>
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<td>Uganda</td>
<td>LDC</td>
<td>Patents Act, 1993. Only formal examination; substantive by ARIPPO for certain fields.</td>
<td>Not excluded</td>
<td>Failure to work; unmet demand; refusal to license, after 3 years; anti competitive practices; also G. use</td>
<td>National</td>
<td>No early working; failure to work; unmet demand; refusal to license; anti-competitive practices; unfair terms or restrictive practices; also G. use</td>
<td>No specific provision</td>
<td>No specific provision</td>
<td>Anti-counterfeiting Legislation</td>
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<td>Zambia</td>
<td>LDC</td>
<td>Patents Act, 1958. Only formal examination.</td>
<td>Not excluded</td>
<td>Failure to work; unmet demand; refusal to license; anti-competitive behaviour; unfair conditions or restrictive terms, after 3 years; also G. use</td>
<td>No explicit provision</td>
<td>No early working; failure to work; unmet demand; refusal to license; restrictive terms; dependents; anti-competitive practices</td>
<td>No specific provision</td>
<td>No specific provision</td>
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<td>Zimbabwe</td>
<td>DC</td>
<td>Patents Amendment Act, 2002. Only formal examination.</td>
<td>Not excluded</td>
<td>Failure to work; unmet demand; refusal to license; restrictive terms; dependents; anti-competitive practices</td>
<td>Inter-national</td>
<td>Yes, early working only.</td>
<td>No specific provision</td>
<td>No specific provision</td>
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