POLICY BRIEF
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KENYA & UGANDA

UTILIZING THE FLEXIBILITIES IN THE TRIPS AGREEMENT TO ADVANCE ACCESS TO MEDICINES

Summary

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement), which sets the minimum standards for protection of intellectual property rights (IPRs), has a set of 'flexibilities' designed to limit the potential effects of IPR protection on access to medicines, especially in low-income countries. Basing on the findings of a study that assessed the implementation of these flexibilities in Kenya and Uganda, this brief argues that the two countries have an opportunity to promote access to medicines by addressing IPRs in national policies, implementing the TRIPs flexibilities that have been incorporated into national laws, and enhancing coordination among key actors at national and regional levels.

Context

As is the case with other developing and least developed countries (LDCs), the health care systems of Kenya and Uganda are struggling to provide treatment for many communicable and non-communicable diseases (NCDs). In Kenya, an estimated 1.6 million people are living with HIV[1], about 1.1 million of whom are enrolled on anti-retroviral treatment (ART), representing 75% coverage.[2] HIV and AIDS accounts for about 15% and 29% of the annual disease burden and deaths, respectively.[3] TB is the single leading cause of death for persons living with HIV (PLHIV) in Kenya; about 35% of TB patients are co-infected with HIV.[4]

1.6 million people are living with HIV in Kenya

In Uganda, HIV prevalence among adults is estimated at 6.2%, and new HIV infections are still 'unacceptably high'.[5] As of June 2016, Uganda had an estimated 1.5 million PLHIV, of whom 0.9 million (60%) were enrolled on ART.[6] In Uganda, an estimated 50% of TB patients are also co-infected with HIV, and as is the case in Kenya, TB is the leading killer of PLHIV.[7]

1.5 million people are living with HIV in Uganda

NCDs constitute a new threat to health systems and pose a new access to medicine crisis due to patents, especially in low and middle-income countries.[8] In Kenya, NCDs already

1 http://blog.opendata.go.ke/hiv-situation-in-kenya/
2 http://www.unaids.org/en/regionscountries/countries/kenya
3 NACC calls for inclusion of HIV in the NHIF to attain Universal Health Care. 24 May 2018, http://nacc.or.ke/2018/05/24/nacc-calls-for-inclusion-of-hiv-in-the-nhif-to-attain-universal-health-care/
4 Centers for Disease Control and Prevention. Kenya exceeds goals to address TB and HIV coinfection. https://www.cdc.gov/globalhealth/countries/kenya/blog/kenya_tb.htm
5 Results of the Uganda Population HIV Impact Assessment (UPHIA) 2016 and Uganda AIDS Indicator Survey (UAIS) 2011
6 Ministry of Health, Uganda, 2018. Consolidated guidelines for prevention and treatment of HIV in Uganda
7 Ministry of Health, Uganda, 2006. National Policy guidelines for TB/HIV collaborative activities in Uganda
8 Bollyky T.J., 2013. Access to drugs for treatment of non-communicable diseases. *PLoS Med* 10(7): e1001485. https://doi.org/10.1371/journal.pmed.1001485

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account for about 27% of deaths.[9] It has been observed that unavailability of medicines in developing countries is affected by many factors, including prohibitive prices, which are partly occasioned by patents.[10]

Key flexibilities in the TRIPs Agreement for Kenya and Uganda

The Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement, one of the agreements that established the World Health Organization (WTO) in 1994, sets the minimum standards for IPR protection that all WTO members are obligated to enforce.[11] However, to mitigate the potential effects of patents on affordability of products from new inventions, the Agreement has a set of flexibilities that LDCs and developing countries can use to achieve their own public policies, such as access to medicines.

Member states are free to determine the grounds upon which they grant compulsory licenses.

Compulsory licenses

Compulsory licensing enables a third party or government agency to use a patented invention without consent from the patent-holder under certain conditions, including proof of failed negotiations for a voluntary license, a case-by-case consideration of applications, and compensation of the patent-holder. A compulsory license may also be granted to address a national emergency, anti-competitive behavior or non-performance of a patent-holder or their licensee. Member states are free to determine the grounds upon which they grant compulsory licenses.

Parallel importation

The TRIPs Agreement gives members freedom to import a patented product from another country where it is marketed by the patent-holder (or with their consent) at a lower price. Given the high prevalence of price discrimination in the marketing of patented products, parallel importation can be an important tool to promote access to affordable medicines.

LDC are not required to grant or enforce patents on pharmaceuticals until 2033

LDC transition period for patents on pharmaceuticals

Unlike Kenya, which is categorized as a developing country, Uganda as an LDC is currently not required to grant or enforce patents on pharmaceuticals until 2033. The spirit of this provision is to allow time for transfer and/or development of technological capacity for local pharmaceutical production in LDCs.

Bolar provision

The 'Bolar provision' allows interested (generic) manufacturers to start producing test-batches of a product before the patent expires. This enables them 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 expires, and thereby enhance competition. The exclusion of therapeutic, surgical and diagnostic methods from being patented also forms part of the flexible provisions available to member states.

The exclusion of surgical and diagnostic devices from being patented is part of the flexibilities

9 http://www.who.int/nmh/countries/ken_en.pdf

10 Ellen t'Hoen, 2002. TRIPS, pharmaceutical patents, and access to essential medicines: A long way from Seattle to Doha. *Chi. J. Int'l L. 27,* 28.

11 Article 27(1) of the TRIPs Agreement.

TRIPs flexibilities in the policy frameworks of Kenya and Uganda

The policy frameworks of both Kenya and Uganda aim to promote the use of IPRs to encourage innovation and technological development. Kenya's Science, Technology and Innovation Policy of 2012 aims to 'develop and implement a robust system of identifying, evaluating, recognizing, protecting IPRs and rewarding excellence in science, technology and innovation activities.'

Unlike Uganda's, Kenya's Health Policy addresses IP and its relevance to access to affordable medicines

On the other hand, Uganda's National Intellectual Property Policy has three objectives: 1) to establish appropriate infrastructure that supports innovation and creativity; 2) to develop human capital for the IP value chain; and 3) to enhance utilization of the IP system. The key elements of the policy are promotion of technology transfer and integration of IP into the productive and service sectors.

Unlike Uganda's, Kenya's Health Policy addresses IP and its relevance to access to affordable medicines. The policy aims to promote use of generics and to exploit 'all provisions' in the TRIPs Agreement. Despite the fact that challenges in accessing ARVs sparked the controversy that culminated into the Doha Declaration on the TRIPs Agreement and Public Health in 2001, neither Kenya's HIV and AIDS Strategic Framework 2014/15-2018/19 nor Uganda's National HIV and AIDS Policy 2011 has any explicit reference to the role of IPR in access to HIV medicines. It is imperative that all national policies that are relevant to access to medicines address IPR.

TRIPs flexibilities in the legal frameworks of Kenya and Uganda

As WTO members, Kenya and Uganda are obligated to protect IPRs through enacting and enforcing national IP laws that are consistent with the TRIPs Agreement. Kenya enacted its Industrial Property Act in 2001, while Uganda enacted hers in 2014, as the main patent laws. Kenya's law provides for compulsory licenses, government use order, voluntary licenses, parallel importation and 'Bolar provision'. Uganda's law incorporates all these flexibilities, as well as the transition period for patents on pharmaceuticals. However, while Uganda's law emphasizes novelty, the patentability criteria in Kenya's law is not considered strict enough to prevent abuse and 'ever-greening' of patents. One of the measures that can be taken is to adopt strict patentability criteria that ensure that only-deserving patents are granted.

Incorporating the TRIPs flexibilities into national laws alone cannot on its own solve IPR-related challenges to access to medicines in developing countries.

Kenya and Uganda have an opportunity to utilize the TRIPs flexibilities that they have incorporated in their national laws to promote access to affordable medicines. Incorporating the TRIPs flexibilities into national laws alone cannot on its own solve IPR-related challenges to access to medicines in developing countries.

There have been effort to manufacture generic ARVs locally: By Cosmos in Kenya and Cipla Quality Chemicals in Uganda, as well as medicines for hepatitis B and NCDs. Cosmos manufacturers Tenofovir-based combinations of generic ARVs as well as anti-hypertensive, anti-diabetic, anti-ulcers and anti-Parkinsons, while Cipla Quality Chemicals manufactures Tenofovir-based and Zidovudine-based combinations of generic ARVs as well as hepatitis B medicines. Kenya has about 35 pharmaceutical manufacturing companies, while Uganda has 15. However, local production has been challenged by inadequate markets and limited technology. Most manufacturers are producing below capacity.

Besides local production, there are many producers of generic medicines globally from which Kenya and Uganda can import from under the parallel importation flexibility. There are generic producers are now spread in many countries, including South America, Asia, Europe, the Middle East and the US. Parallel importation is hence possible but it is yet to be exploited to promote access to affordable medicines.

The use of compulsory licenses has been frustrated by complex preconditions set out in legislation.[12] There has been an attempt to utilize the compulsory licensing in Kenya by Cosmos to produce a generic version of an ARV drug patented by Glaxo SmithKline (GSK) and Boehringer Ingelheim. However, rather than wait for Government to issue the license, the two companies decided to grant Cosmos a voluntary license.[13] However, it was not economically viable for Cosmos to exploit the voluntary license after GSK and Boehringer reduced the prices of their medicines in Kenya, thus frustrating the utilization of this flexibility.[14] Roche subsequently launched a program to provide free medicines to Kenya, further undermining Cosmos' market.

Coordination of IP and IP-related institutions

Enhancing coordination between national IP institutions and ARIPO, as well as with other relevant national institutions is critical for ensuring that policies, laws and practices are harmonized and consistent.

In terms of the institutional frameworks, Kenya Industrial Property Institute (KIPI), established by the Industrial Property Act 2001, is the main IP institution in Kenya, while Uganda Registration Services Bureau (URSB) is a statutory body with the mandate to administer IPR in Uganda. These institutions receive and consider IPR applications, and grant, register and administer IPRs, among other functions.

However, the capacity of these institutions to assess patent applications is still limited. Hence, they continue to depend on the African Regional Intellectual Property Organization (ARIPO) for the service. The legal frameworks of the two countries recognize patents issued by ARIPO. In the case of Kenya for instance, Article 59 of the Industrial Property Act 2001 states that 'A patent, in respect of which Kenya is a designated state, granted by ARIPO by virtue of the ARIPO Protocol shall have the same effect in Kenya as a patent granted under this Act…' However, there has been limited coordination between ARIPO and national institutions which has resulted in ARIPO granting patents on pharmaceuticals on behalf of Uganda despite LDCs having an exemption.

Enhancing coordination between national IP institutions and ARIPO, as well as with other relevant national institutions, such as the ministries responsible for health, trade and industry, drug regulatory authorities, professional bodies and research institutions is critical for ensuring that policies, laws and practices are harmonized and consistent. This will avoid instances where proposed anti-counterfeit and competition laws have threatened access to generic medicines. At the regional level, the East African anti-counterfeit law contains several TRIPs-plus provisions, including an overly broad definition of counterfeits that encompasses generic medicines.

Conclusion

Although Kenya and Uganda belong to different socioeconomic levels, each of them has an opportunity to utilize the TRIPs flexibilities that have been incorporated into national laws. IP needs to addressed in all relevant laws, and TRIPs-plus provision in new laws and bilateral trade agreements avoided at all costs. Capacities to assess patents applications needs to be built, and coordination of IP and relevant institutions at national and regional levels strengthened. Kenya and Uganda should consider cooperation at the level of East African Community to broaden the market for locally produced medicines and cooperative research and development. Marshalling resources to put into effect the EAC Regional Pharmaceutical Manufacturing Plan of Action 2017-2027 is a good point start from. Finally, Kenya and Uganda need to be more creative in incorporating into national laws and policies concepts that the TRIPs Agreement simply mentions but does not define. Such concepts include novelty and inventiveness; situations of extreme urgency for the purposes of compulsory licensing; and others.

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12 P Ogendi 'Access to essential medicines and the utilization of compulsory licensing and parallel importation in Kenya and South Africa' Unpublished LLM thesis, University of Nairobi, (2013) 74-75.

13 Ben Sihanya 'Patents, Parallel importation and compulsory licensing of HIV/AIDS Drugs: The experience of Kenya' (undated) *Managing the challenges of WTO participation,* https://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm

14 L Opati 'Intellectual property rights in health – impact on access to drugs' in M Wekesa & B Sihanya *Intellectual property rights in Kenya* (2009) 29-30. Konrad Adenuer Stiftung.