UTILIZING FLEXIBILITIES IN THE TRIPs AGREEMENT TO ADVANCE ACCESS TO MEDICINES IN KENYA AND UGANDA

Challenges and Opportunities for Access to Medicines for HIV, TB, Hepatitis and Non-Communicable Diseases

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Cover photo: Participants at the regional meeting of intellectual property rights stakeholders who validated this research. Photo credit: Richard Hasunira @ Hasunira

Executive Summary

Introduction

The Agreement on Trade-Related Intellectual Property Rights (TRIPs Agreement) set minimum standards for protection intellectual property rights (IPRs) for all fields of technology, including the pharmaceutical sector. However, to limit the potential effects of strong IPR protection on access to medicines, it provides for a set of flexibilities, including compulsory licensing, parallel importation, 'bolar provision', and a transition period during which least developed countries (LDCs) do not have to grant patents on pharmaceuticals.

Objective

The overall objective of this study was to assess the extent to which Kenya and Uganda have implemented the TRIPs flexibilities and the effect of patents on the prices of medicines for HIV, tuberculosis (TB), cancer and Hepatitis C.

Methodology

A desk review was conducted to assess the extent to which the legal, policy and institutional frameworks have incorporated the TRIPs flexibilities.

Secondary data on patents and prices of 75 selected medicines for HIV, opportunistic infections, TB, cancer and hepatitis C was obtained from online resources. Medicine price information was extracted from the Management Sciences for Health (MSH) International Drug Price Indicator Guide.

Primary data was collected through field interviews with representatives of national intellectual property offices, pharmaceutical manufacturers, country offices of the World Health Organization (WHO), the ministries responsible for trade and health, and research institutions.

TRIPs flexibilities in the legal and policy frameworks

The policy frameworks of both Kenya and Uganda aim to promote the use of intellectual property rights (IPRs) to encourage innovation and technological development. Kenya's policy for science, technology and innovation of 2012 aims to 'develop and implement a robust system of identifying, evaluating, recognizing, protecting intellectual property rights (IPRs) and rewarding excellence in science, technology and innovation activities.'

There has been minimal exploitation of any legal reforms to aid access to affordable medicines due to limited technological and manufacturing capacity of Kenya and Uganda.

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.

On the side of the legal frameworks, Kenya enacted its Industrial Property Act in 2001, while Uganda enacted hers in 2014, as the principal patent laws. Kenya's Industrial Property Act 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 pharmaceutical. However, while Uganda's law emphasizes novelty, the patentability criteria in Kenya's law is not considered strict enough to prevent abuse.

However, incorporating the TRIPs flexibilities into national laws alone cannot on its own solve IPR-related challenges to access to medicines in developing countries. There has been minimal exploitation of any legal reforms to aid access to affordable medicines due to limited technological and manufacturing capacity of Kenya and Uganda. There must be deliberate initiatives at the global, regional and national levels to implement these provisions.

At the regional level, the African Union and the East African Community (EAC) have both encouraged member states and given guidance to make use of the TRIPs flexibilities and avoid TRIPs-plus measures in trade agreements. However, the East African anti-counterfeit law contains several TRIPs-plus provisions, including an overly broad definition of counterfeits that encompasses generic medicines.

Another challenge has been limited capacity of East African countries to examine patent applications, which has made them rely on the Africa Regional Intellectual Property Organization (ARIPO), which has reportedly granted some patents on behalf Uganda despite LDCs having an exemption.

In terms of the institutional frameworks, Kenya Industrial Property Institute (KIPI), established by the Industrial Property Act 2001, is the main IP office 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.

Patent status of medicines

In Kenya, out of 140 possible patents on 21 ARV products, 23 patents had been granted and were still valid. Manufacturers of ARVs had not filed for 47 patents, and 70 patents had expired by the time of the study. On the other hand, out of 116 possible patents on 19 ARVs in Uganda, 16 had been granted and were still valid; 42 had not been filed; and 58 had expired.

The link between patent status and prices was mixed, but newer medicines which were more likely to be on patent overall had higher international supplier prices. ARV prices increased with newer medicines and with medicines for second and third line treatment.

However, in at least one case, one third line ARV (Raltegravir) for which a patent had not been filed was more expensive (USD 52.13 for 60 tablets) than another third line ARV on patent (Etravirine), which costs USD 37.98 for 112 tablets. For XDR TB, a dose of the preferred medicine, Bedaquiline, costs up to USD 3000. The price of patented newer treatments for Hepatitis C was very high.

The link between patent status and prices was mixed, but newer medicines which were more likely to be on patent overall had higher international supplier prices.

Summary of recommendations

1) Institutional collaboration between the ministries of Health, IP office and regulatory institutions should be strengthened to protect and promote access to essential medicines.

2) Kenya and Uganda should explore using the EAC platform to utilize TRIPS flexibilities to produce or procure generic medicines to the benefit all member states.

3) Kenya and Uganda EAC should ensure that anti-counterfeit legislation and bi-lateral trade agreements do not hamper legitimate trade in generic medicines.

4) As an LDC, Uganda should not grant or enforce patents on pharmaceutical products at all.

5) The civil society should advocate for, and engage policymakers on, the full utilization of TRIPS flexibilities.

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Acronyms and Abbreviations

ACHPR	African Charter on Human and Peoples' Rights
ARIPO	African Regional Intellectual Property Organization
ART	Anti-retroviral treatment
CSOs	Civil society organizations
EAC	East African Community
EML	Essential Medicines List
GATT	General Agreement on Tariffs and Trade
GDP	Gross domestic product
HRC	Human Rights Council
ICESCR	International Convention on Economic, Social and Cultural Rights
IPRs	Intellectual Property Rights
KASF	Kenya AIDS Strategic Framework
LDC	Least Developed Countries
MPP	Medicines Patent Pool
NCDs	Non-communicable diseases
NGOs	Non-governmental organizations
PEP	Post-exposure prophylaxis
PLHIV	People living with HIV
PrEP	Pre-exposure Prophylaxis
R&D	Research and Development
TRIPs	Trade-Related Aspects of Intellectual Property Rights
ULRC	Uganda Law Reform Commission
UNBS	Uganda National Bureau of Standards
UNMHCP	Uganda National Minimum Health Care Package
UPHIA	Uganda Population-based HIV Impact Assessment
URSB	Uganda Registration Services Bureau
USD	United States dollars
WTO	World Trade Organization

1. Introduction

1.1 Background to the research problem

In the East African Community (EAC), Kenya has the largest economy and is the only one classified as a middle-income country, with a GDP of USD 85.9 billion and a GDP per capita of USD 1,790.[1] The country has an estimated population of 49.7 million people, of whom about 17.4 million live under the international poverty line[2] (or 36.1% of population; 2015 estimate).[3] On the other hand, Uganda is a least developed country (LDC), with a GDP of USD 25.9 billion and a GDP per capita of USD 604 (2017 est.).[4] The country has an estimated population of 42.9 million (2017 est.), of whom 17.3 million Ugandans (41.6% of the population) are living below the international poverty line.[5]

Kenya and Uganda have a total of 34.7 million extremely poor people, who struggle to get life's basic necessities and face challenges accessing medicines in the private sector, where they are unaffordable to the poor, and have to rely on the public sector, where stock-outs are rampant. Access to medicine is the foundation of human advancement because it reduces morbidity and mortality and improves the quality of life for millions of people around the world.[6] Under human rights principles, everyone has the right to access essential commodities like medicines; access to essential medicines has been widely defined to constitute the right to health.[7]

T'Hoen[8] observes that unavailability of medicines in developing countries is affected by many factors, including "logistical supply and storage problems, substandard drug quality, inappropriate use, inadequate production and prohibitive prices." However, prohibitive prices are also occasioned by the protection of intellectual property rights (IPRs).[9]

Kenya and Uganda have a total of 34.7 million extremely poor people, who struggle to get life's basic necessities and face challenges accessing medicines in the private sector, where they are unaffordable to the poor, and have to rely on the public sector, where stock-outs are rampant.

As is the case in other least developed and developing countries, the health care systems in Kenya and Uganda are under a heavy burden of providing treatment for many communicable and non-communicable diseases (NCDs), including HIV and AIDS, tuberculosis (TB), hepatitis, cancers, cardiovascular diseases, diabetes and others.

Both Kenya and Uganda are among HIV high-burden countries. In Kenya, HIV prevalence is estimated at 6% and the number of people living with HIV (PLHIV) is estimated at 1.6 million.[10] HIV and AIDS accounts for about 15% and 29% of the health burden and annual deaths, respectively.[11] In Uganda, results from Uganda Population-based HIV Impact Assessment (UPHIA) 2016-2017 show that overall HIV prevalence among adults aged between 15-49 years is estimated at 6.2%.[12] UPHIA acknowledges that HIV infections are still unacceptably high in Uganda.

In the initial years, access to HIV treatment was constrained by prohibitive prices. The emergence of generic anti-retroviral medicines (ARVs) around 2000 contributed to a reduction in prices from about USD 10,000 per patient per year (the lowest publicly announced originator price) to about USD 350 in 2001.[13] Despite the fact that more people than ever before are enrolled on anti-retroviral treatment (ART), Kenya and Uganda are yet to achieve universal access to ART. Currently, about 1,121,938 PLHIV in Kenya are enrolled on ART, representing about 75% coverage.[14]

1 Kenya National Bureau of Statistics. Economic survey 2018. https://www.knbs.or.ke/download/economic-survey-2018/
2 The international poverty line is set at US$1.9 per day in 2011 Purchasing Power Parity
3 The World Bank: Poverty and Equity Data Portal
4 World Back. Uganda country data, GDP (current prices). https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?locations=UG&view=chart
5 The World Bank: Poverty and Equity Data Portal
6 Ogunaobi (2018) Broadening the conversation on the TRIPS agreement: Access to medicines includes addressing access to medical devices, journal of World Intellectual Property pg. 70-87 available at willeyonlinelibrary.com/journal/jwip
7 Article 12 (1) The International Covenant of Social, Cultural and Economic Rights
8 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.
9 As above, 27.
10 http://blog.opendata.go.ke/hiv-situation-in-kenya/ (accessed 15 October 2018).
11 '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/
12 Results of the Uganda Population HIV Impact Assessment (UPHIA) 2016 and Uganda AIDS Indicator Survey (UAIS) 2011
13 Ellen 't Hoen, Jonathan Berger, Alexandra Calmy& Suerie Moon (2011). Driving a decade of change: HIV/AIDS, patents and access to medicines for all. *Journal of the International AIDS Society.* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078828/
14 http://www.unaids.org/en/regionscountries/countries/kenya

By the end of June 2016, Uganda had an estimated 1.5 million PLHIV, of whom 898,197 (60%) were enrolled on ART.[15]

PLHIV are also facing co-infections. Among PLHIV in Kenya, TB is the single leading cause of death, with more than 35% of those with TB co-infected with HIV.[16] In Uganda, an estimated 50% of TB patients are also co-infected with HIV, TB is a leading killer of PLHIV.[17] PLHIV are living longer and healthier lives but are now at risk for morbidity and mortality from NCDs.[18] In addition, recent research has also indicated that in the next 20 years, NCDs are expected to overtake communicable disease as the leading cause of death in sub-Sahara Africa.[19] Indeed, as NCDs increasingly become a global health concern, Bollyky[20] warns of a new access to medicine crisis with controversy over patented NCD medicines, especially in low and middle-income countries where it is still difficult for millions of people to access lifesaving medicines.

NCDs have in the recent past presented unique challenges in the health system accounting for about 27% of deaths or almost 100,000 out of 369,000 people per year in Kenya.[21] It is estimated that by 2030, cardiovascular diseases, cancer and diabetes will account for about 60% of deaths in Kenya.[22] In this regard, apart from HIV and TB, the Kenya Health Policy 2012-2030 recognizes that NCDs "represent an increasingly significant burden of ill health and death in the country".[23] The Policy also acknowledges that NCDs accounted for 50-70% of all hospital admissions and up to half of all inpatient deaths.[24]

Organ-specific NCDs that affect PLHIV include pulmonary arterial hypertension, lung cancer, coronary artery disease, thyroid disease, Addison's disease, pancreatitis, HIV dementia, osteonecrosis, joint malignancy, myositis and retinal microvasculopathy.[25]

PLHIV are living longer and healthier lives but are now at risk for morbidity and mortality from NCDs... In the next 20 years, NCDs are expected to overtake communicable disease as the leading cause of death in sub-Sahara Africa

Prices of medicines are high and treatment is unaffordable, and availability is unreliable in many developing countries.[26,27] In addition, access to newer, more effective ARVs with less side effects is still a major challenge due to prohibitive prices. And given the dwindling international funding in the health sector, it is estimated that around 830,000 people in Africa, including Kenya and Uganda, will not be able to access ART in the near future.[28] Yet PLHIV also face the threat of co-morbidities from NCDs, for which they need medicines.

According to the social contract theory, intellectual property (IP) is a contract between society and innovators.[29] Society recognizes that innovation is socially beneficial and that the knowledge underlying innovation is intangible. Given that the knowledge is intangible, innovators may have difficulty capturing the rewards from innovation. Without rewards, innovators may stop innovating and society loses out. The solution to reward innovators is the IP system.

However, patents on pharmaceutical products and processes provide drug companies with monopolies over the production and marketing of medicines, allowing them to fix prices at high rates.[30] Millions of people are denied access to medicines by high prices.[31]

15 Ministry of Health, Uganda, 2018. Consolidated guidelines for prevention and treatment of HIV in Uganda

16 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

17 Ministry of Health, Uganda, 2006. National policy guidelines for TB/HIV collaborative activities in Uganda

18 Hyle E.P., Naidoo K., Su A.E., El-Sadr W.M., and Freedberg K.A., 2015. HIV, TB and NCDs: What is known about the costs, effects, and cost-effectiveness of integrated care? *Journal of AIDS.* J Acquir Immune Defic Syndr. 2014 Sep 1; 67(0 1): S87–S95.

19 The civil society benchmark report (2014)

20 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

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

22 'First Kenya National Forum on NCDs concludes with the Naivasha Call for Action'. *NCDAlliance* (30 August 2011), https://ncdalliance.org/node/3499 (accessed 23 August 2018).

23 Kenya Health Policy 2012-2030, 5.

24 Kenya Health Policy 2014-2030, 10-11.

25 R. Dawson, W. N. Rom, K. Dheda & E. D. Bateman (2013). The new epidemic of non-communicable disease in people living with HIV. *Public Health Action*. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4463081/

26 The Lancet, 2016. Essential Medicines for Universal Health Coverage: The Lancet Commission on Essential Medicines Policies

27 World Health Organization, World medicines situation report, (2011) 12, http://apps.who.int/medicinedocs/documents/s18065en/s18065en.pdf (accessed 5 April 2016).

28 'Now experts concerned about cut in HIV funding' *Daily Nation,* 23 July, 2017, https://www.nation.co.ke/news/Now-experts-concerned-about-cut-in-HIV-funding/1056-4028882-n7rwghz/index.html

29 The IPK at, 2011. An economic perspective on IP: The social contract theory of IP. http://ipkitten.blogspot.com/2011/11/katanomics-1-economic-perspective-on-ip.html

30 Cecilia Oh (2001). TRIPS, patents and access to medicines: Proposals for clarification and reform. *Third World Network Briefing Paper.* http://www.twn.my/title/drugs2.htm

31 StopAids. Access to medicines. https://stopaids.org.uk/our-work/hiv-in-international-development/access-to-medicines/

Hence, developing countries and LDCs have an opportunity to utilize or facilitate the utilization of the TRIPS flexibilities as contained in the Doha Declaration on TRIPS and Public Health (2001) and the existence of patents should not hamper access to affordable medicines.

1.2 Study objectives

The overall objective of this study was to assess the extent to which Kenya and Uganda have implemented of the TRIPs flexibilities and the effect of patents on the prices of medicines for HIV, tuberculosis (TB), cancer and Hepatitis C.

1) Assess the current status of the implementation of TRIPS flexibilities in Kenya and Uganda's legal and policy frameworks;

2) Ascertain the patent status of selected medicines for HIV, TB, NCDs and Hepatitis in Kenya and Uganda;

3) Analyze any linkages between the patent status of selected medicines and their prices.

1.3 Methodology

1.3.1 Study design

The study was a mixed methods study. Quantitative data was collected on HIV, opportunistic infections, tuberculosis, cancer and hepatitis C medicine patents and prices while qualitative data was gathered through a desk review of existing literature, laws and policies on intellectual property. Primary data was collected through field interviews and focus group discussions (FGDs).

1.3.2 Data sources

A desk review was conducted of the legal, policy and institutional framework relevant to the study topic. This included the TRIPS Agreement and Doha Declaration; the International Covenant of Social, Cultural and Economic Rights and other human rights instruments; the EAC Charter and second Regional Pharmaceutical Plan of Action 2017; the national constitutions of Kenya and Uganda, the IP laws; and peer-reviewed articles, official reports, essential medicine lists (EML) and HIV treatment guidelines of the two countries, and other literature.

Data on medicine patent status and prices was obtained from online resources between 28 August 2018 and 9 September 2018. Patent information including description and strength of medicine, description/ details of patent such as number, patent status (filed, granted, expired) and date of expiry were sourced from the online Medicines Patents and Licenses Database (MedsPal, http://www.medspal.org).

Patent information was compared with prices of international supplier or buyer prices for patient packages of medicines for supply of one month's refill or dose of treatment.

Medicine price information was extracted from the Management Sciences for Health (MSH) International Drug Price Indicator Guide accessed at http://msh-priceguide.org/en/drug-search-page-2/.

Only medicine prices available in the MSH International Drug Price Indicator Guide were included in the analysis. Analysis was made of the number patents not filed, granted and expired. Patent information was compared with prices of international supplier or buyer prices for patient packages of medicines for supply of one month's refill or dose of treatment.

Primary data were gathered from key informants through personal interviews. The respondents were from national intellectual property offices, pharmaceutical manufacturers, country offices of the World Health Organization (WHO), the ministries responsible for trade, ministries of health and research institutions.

1.3.3 Data collection procedures

We prepared a medicine list of 75 medicines for the study based on the EML and HIV treatment guidelines of the two countries. The list included 44 medicines for HIV, four medicines for opportunistic infections, 15 anti-TB medicines, four anticancer medicines, and eight hepatitis C medicines.

The study team logged onto the portal (http://www.medspal.org) and fed individual medicine names using International Nonproprietary Name (INN) and strength into the product or keyword search engine, specifying the country whose medicine patent was being searched. The search results were then retrieved with details on product strength, patent description, license, patent application number, patent expiry date and patent status.

Key areas that informed the original data extraction tool included generic name, patent number, nature of protection, foreign priority date, filing date, patent expiry date and the patent status.

The data extraction tool was modified to include additional areas that were found on the online database including medicine strengths, patent description, license description and innovation title that informed the final data extraction tool.

For medicine price information, the product name was fed into search engine at http://mshpriceguide.org/en/drug-search-page-2/. Procurement price (in USD) of the product (with the strength of choice) was chosen from the list. Procurement prices are provided as either median supplier or buyer prices.

The preliminary findings of the study were validated at a stakeholder meeting held 6-8 November 2018. The meeting was attended by 35 representatives of civil society, IP consultants and government officials.

1.3.4 Data analysis

We examined medicines extracted from the database (MedsPal) for status of patents, patent description, number of patents, and year of patent expiry. We matched medicines with supplier prices and/or buyer prices in USD from the MSH international drug price indicator guide.

Medicines were matched with supplier prices and/or buyer prices in USD from the MSH international drug price indicator guide.

1.3.5 Ethical consideration

Written or verbal informed consent was obtained from all respondents. Information obtained has been treated confidentially and names have not been used in this report though positions of the respondents may have been referred to. Permission to use quotes in the study was obtained during the informed consent process. Information collected was used only for the purpose of the study.

2. TRIPs Flexibilities in the Legal and Policy Frameworks

2.1 The global and regional intellectual property rights framework

Kenya and Uganda are both members of the East African Community (EAC), the African Regional Intellectual Property Organization (ARIPO) and World Trade Organization (WTO), and signatories of the Trade-related Aspects of Intellectual Property Rights (TRIPs) Agreement, one of the agreements that established the (WTO) in 1994. The East African Treaty[32] requires partners to harmonize their national health policies and regulations in order to promote exchange of information but also to cooperate in development of pharmaceutical products[33], among others.

The TRIPs Agreement set minimum standards for IPR protection of both process and product patents in all fields of technology, including the pharmaceutical sector.[34] As WTO members, Kenya and Uganda are obligated to protect IPRs through enacting and enforcing national intellectual property (IP) laws that are compliant with the TRIPs Agreement.

In the beginning, the TRIPs Agreement raised fears among developing and least developed countries (LDCs) that it could impede access to medicine by giving monopoly powers to producers in technologically advanced countries to raise prices and make medicines unaffordable to people in low-income countries. The negotiations that followed resulted into the incorporation of a set of safeguards in the Agreement commonly referred to as "TRIPS flexibilities".

Article 7 of the TRIPS Agreement in particular emphasizes that enforcement and protection of IPR should promote transfer of technological innovation to the advantage of the users and producers in a manner that is conducive to social and economic welfare and to a balance of rights and obligations. To support that position, Article 8 encourages WTO members to formulate laws and regulations and adopt necessary measures that protect public health. One of the measures that can be taken by WTO members is to adopt strict patentability criteria that ensure that only-deserving patents are granted and that "ever-greening" patents is discouraged.

Compulsory licensing[35] is one of the key flexibilities that low and middle income countries can use to promote access to medicine. This provision gives WTO members authority to grant the right to use a patent without permission from the patent holder under certain conditions. A government can also use a patent without the consent of the patent holder for its own purposes. This is also referred to as 'government use'. In both cases, royalties are payable to the patent holder.

The TRIPS Agreement emphasizes that enforcement and protection of IPR should promote transfer of technological innovation to the advantage of the users and producers in a manner that is conducive to social and economic welfare and to a balance of rights and obligations.

However, utilization of compulsory licensing became difficult and poor countries that attempted to make use of it experienced a lot of pressure from nations with patented medicines. In 2001, the Doha Declaration[36] clarified that members have the freedom to determine the grounds upon which to grant compulsory licenses.

Another challenge was that under Article 31(f) of the TRIPs Agreement, medicines produced under compulsory license were to be limited to the domestic market. This provision made the flexibility redundant for countries that have limited market capacity and found it more visible to import from other developing countries, such as Brazil and India that produce affordable generic medicines. The Doha Declaration (paragraph 6) recognized the problem and promised a solution which came in the form of the Decision of 30th August 2003 which introduced a special compulsory license for exports.[37]

Other key flexibilities in the TRIPS Agreement include "parallel importation" and "bolar provision". Parallel importation allows low-income countries to purchase a patented medicine from a third party country if it is accessible at a lower price, while the bolar provision gives exceptions for research and market approvals for purposes of expedited market entry when patent eventually expires.

32 Treaty Establishing the East African Community
33 Article 118 of the East African Treaty
34 Article 27(1) of the TRIPs Agreement.
35 Article 31 of the TRIPS Agreement
36 Article 5 of the Doha Declaration
37 WTO. TRIPS and public health: notifications. https://www.wto.org/english/tratop_e/trips_e/public_health_e.htm

The exclusion of therapeutic, surgical and diagnostic methods from being patented also forms part of the flexible provisions available to WTO members.

The most relevant flexibility is possibly the waiver granted to LDCs, given that Uganda and other East African countries save Kenya, are categorized as LDCs. Under Article 66 (1), LDCs are not required to implement the provisions of the TRIPS Agreement during the transition period, which in respect of pharmaceuticals patents, has since been extended to 2033. The spirit of this provision however, is to allow transfer of technology by the developed countries in order to facilitate the development of pharmaceutical manufacturing capacity in LDCs.

Uganda has made an attempt to utilize the LDC transition period to grow its manufacturing capacity through a partnership between CIPLA and Quality Chemicals, currently producing generic medicines for HIV and malaria. However, this has not yet translated into cheaper medicines.[38]

Further affirmation of the available policy space was made through the Doha Declaration of 2001 which gave primacy to public health interests over individual rights of patent holders. Paragraph 4[39] categorically stated that;

> *"… the TRIPS Agreement does not and should not prevent members from taking measures to protect public health and it should be interpreted and implemented in a manner supportive of WTO members' right to protect public health, in particular access to medicine for all."*

Despite this policy space, there is fear that Free Trade Agreements between developing and developed countries pose a risk of undermining the effective use of TRIPS flexibilities for public health.[40] Although WTO members are not under any obligation to protect IPRs beyond what is provided under the Agreement[41], reports indicate that the ability to utilize the TRIPS flexibilities is being gradually eroded by various bilateral and regional agreements being negotiated with developed countries.[42] Developing countries are constantly faced with the dilemma of entering into agreements with "TRIPs-plus" provisions as precondition for accessing some foreign markets, which is undermining the utilization of TRIPs flexibilities to protect public health in their own countries.

38 Flavia Nassaka (2016). NMS, Cipla bickering over expensive HIV/AIDS drugs. *The Independent, October 25, 2016*

39 Doha Declaration on TRIPS Agreement and Public Health

40 Musungu, S.F. & Oh, (2006). The Use of Flexibilities in Trips by Developing Countries: Can they Promote Access to Medicines?

41 Article 1 TRIPS Agreement

42 Guidelines for Implementation of Trips Flexibilities in National Legislation to Improve Access to medicines in the West African Region published in October 2012 by West Africa Health Organization

The East African Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO Flexibilities and the Approximation of National Intellectual Property Legislation encourages and guides EAC member states to incorporate TRIPs flexibilities into their national laws

These concerns among others, have prompted a number of initiatives by different international bodies including UN agencies. In 2008, the World Health Assembly adopted Resolution 61:21 which endorsed the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property with the aim of improving the delivery of, and access to, health products by overcoming barriers to access. This strategy acknowledged the importance of Article 7 of the TRIPs Agreement and emphasized the need for technology transfer.

In July 2010, Unitaid established the Medicines Patent Pool (MPP), which MPP negotiates with patent holders for production licenses for medicines for HIV, hepatitis C and tuberculosis. These licenses enable lower-cost manufacturers to produce and distribute patented medicines in developing countries and LDCs, including Kenya and Uganda. As of 2018, the MPP held licenses for 13 HIV ARVs, two HCV ARVs and one investigational treatment for TB from several patent holders, including AbbVie, Bristol-Myers Squibb, Gilead Sciences, MSD, Viiv Healthcare, and others.[43]

In 2013, the EAC developed the East African Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO Flexibilities and the Approximation of National Intellectual Property Legislation. This policy encourages and guides member states to incorporate TRIPs flexibilities into their national laws. The TRIPS Agreement requires WTO members to incorporate the flexibilities into their national laws if they are to utilize them.

The expected outcome of the policy is to enable member states optimise access to health products and medical devices, achieve public health objectives, broaden public domain in order to ensure that health products and services affected by IPRs are available and accessible at affordable prices to people of East Africa, as well as promote pharmaceutical manufacturing and innovation industries in the region.

43 William New. Medicines Patent Pool Nails Down Another Key Pediatric Drug. Intellectual Property Watch, 24/02/2015. https://www.ip-watch.org/2015/02/24/medicines-patent-pool-nails-down-another-key-paediatric-drug/

The African Union also created a roadmap which has three strategic pillars which include access to medicines, local production and regulatory harmonization where members are encouraged to incorporate TRIPs flexibilities and avoid TRIPs-plus measures in trade agreements.

However, some regional engagements pose their own set of challenges. While the EAC has exhibited strong political will to promote access to essential medicines as reflected by the policy and guidance on the utilization of TRIPs flexibilities, there are fears that the East African anti-counterfeit law may undermine the utilization of the flexibilities. The law contains several TRIPs-plus provisions, including an overly broad definition of counterfeits that encompasses generic medicines.

Another challenge has been limited capacity of East African countries to examine patent applications, which has made them rely on ARIPO, which has reportedly granted some patents on behalf Uganda despite LDCs having an exemption.

Kenya enacted the Industrial Property Act in 2001, while Uganda enacted its Industrial Property Act in 2014, incorporating TRIPS flexibilities. These laws constitute the main frameworks for the domestic implementation of IPRs in line with member-state obligations under the TRIPs Agreement. However, incorporating the TRIPs flexibilities into national laws alone cannot on its own solve IPR-related challenges to access to medicines in developing countries and LDCs. There must be deliberate initiatives at the global, regional and national levels to implement these provisions.

2.2 Kenya's legal, policy and institutional framework

The policy and legislative environment is crucial in facilitating the full utilization of TRIPs flexibilities. In this subsection, we review Kenya's legal and policy framework in order to establish the opportunities and gaps on access to medicines in Kenya.

2.2.1 National policy

Vision 2030

Vision 2030 is the 'vehicle for accelerating transformation of [Kenya] into a rapidly industrializing middle-income nation by the year 2030.'[44] Vision 2030 therefore, has three main pillars: economic and macro pillar; political pillar; and social pillar. The social pillar recognizes the health sector and specifically health products and technologies. The Vision 2030 document also identifies the following strategies aimed at ensuring 'quality drugs and commodities for service delivery':

44 http://vision2030.go.ke/.

The Government of Kenya's "the big four" agenda of food security, affordable housing, manufacturing, and affordable healthcare for all, especially the latter two components) is relevant to access to medicines

- Defining and applying an evidenced-based essential package of health products and technologies; Kenya's essential health package is expected to rely on among other things generic medicines, which will require that Kenya fully utilizes the TRIPs flexibilities.
- Establishing rational appraisal mechanism for health product and technologies, to ensure that generic medicines are easily accessible in Kenya.
- Promoting local production, research and innovation of essential health products and technologies, which will require the utilization of the flexibility on production of generic medicines locally.
- Ensure availability of affordable, good quality health products and technologies, which will require the availability of generic medicines in the country.

Vision 2030 is being implemented in stages through medium terms plans. In 2018, Government of Kenya launched the third medium term plan laying out "the big four" agenda of food security, affordable housing, manufacturing, and affordable healthcare for all. The manufacturing as well as affordable healthcare for all agenda are particularly relevant to access to medicines.

Kenya AIDS Strategic Framework 2014/15

The main policy document for HIV and AIDS is the Kenya AIDS Strategic Framework (KASF) 2014/15-2018/19.[45] The vision of KASF is '[a] Kenya free of HIV infections, stigma and AIDS-related deaths.' One of the priority areas is to increase coverage of care and treatment and reduce the loss in cascade of care. The document warns that the increase in the number of people under care and treatment will impose a heavy burden on the health system in Kenya at both

45 'Kenya AIDS Strategic Framework (KASF) 2014/15-2018/19'https://nacc.or.ke/wp-content/uploads/2015/09/KASF_Final.pdf (accessed 2 October 2018)

the national and sub-national levels.[46] There is no mention of the effects of IPR on access to ARVs or any other medicines.

Kenya Health Policy

The Kenya Health Policy covers the issue of access to medicines from an IPR point of view. It provides as follows: *"Ensuring availability of affordable, good quality health products and technologies. This shall be done through full application of all options (e.g., promoting use of generics and exploiting all provisions in the trade-related aspects of intellectual property rights) and public health safeguards relating to health products and technologies, through multi-sectoral interventions on trade, agriculture, food, and related sectors."*[47]

Whereas these provisions may require the full utilization of the TRIPs flexibilities since health products and technologies need to be affordable by policy, there is need to comprehensively address IPR issues and access to medicines issues in the policy.

Policy framework for science, technology and innovation

Kenya's policy framework for science, technology and innovation was put in place in 2012 aiming to transform Kenya into a knowledge-based economy in line with Vision 2030.[48] The policy is based on the principle of reward and recognition, elaborated as follows: 'Develop and implement a robust system of identifying, evaluating, recognizing, protecting intellectual property rights and rewarding excellence in science, technology and innovation activities.'[49] However, the policy fails to recognize the need to access innovation, including through full utilization of TRIPs flexibilities.

Guidelines for Management of Tuberculosis and Leprosy 2013

The Guidelines for Management of Tuberculosis and Leprosy in Kenya of 2013[50] recognize that proper treatment with anti-TB medicines is important in reducing mortality to less than 5%.[51] The policy however, is silent about issues of IPR and access to newer TB treatment.

46 As above, 26.

47 Kenya Health Policy 2014-2030, 52, http://publications.universalhealth2030.org/uploads/kenya_health_policy_2014_to_2030.pdf

48 Republic of Kenya Ministry of Higher Education, Science Technology, 'A policy framework for science, technology and innovation' (2012)

49 As above, 12.

50 'Guidelines for Management of Tuberculosis and Leprosy in Kenya' (July 2013), http://guidelines.health.go.ke:8000/media/TB_Treatment_GUIDELINES_2013.pdf (accessed 24 October 2018).

51 As above.

Kenya's NCD strategy identifies interventions for ensuring availability and affordability of quality, safe and efficacious basic technologies for screening, diagnosis, treatment and monitoring of NCDs. These interventions call for utilization of TRIPs flexibilities

National Strategy for the Prevention and Control of Non-Communicable Diseases, 2015-2020

The National Strategy for the Prevention and Control of Non-communicable Diseases 2015-2020 recognizes that poor availability and affordability of quality, safe and efficacious basic technologies and medicines for screening, diagnosing, treating and monitoring NCDs is a major bottleneck in NCD prevention and control.[52] Consequently, the strategy sets out activities for ensuring availability and affordability of quality, safe and efficacious basic technologies for screening, diagnosis, treatment and monitoring of NCDs at the nation and county levels;[53] and for ensuring availability of essential NCDs prevention and care medicines and supplies and link this to financing mechanisms to foster access, affordability and sustainability at the national and county levels.[54] These interventions may call for utilization of TRIPs flexibilities in Kenya.

2.2.2 National laws

HIV and AIDS Prevention and Control Act, 2006

The HIV and AIDS Prevention and Control Act, 2006[55] was enacted to 'provide measures for the prevention, management and control of HIV and AIDS; to provide for the protection and promotion of public health and for the appropriate treatment, counseling, support and care of persons infected or at risk of HIV and AIDS infection; and for connected purposes.' Section 19(2) of the Act expressly guarantees access to affordable treatment for HIV or AIDS as follows: *'The Government shall, to the maximum of its available resources, take the steps necessary to ensure the access to essential healthcare services, including the access to essential medicines at affordable prices by persons with HIV or AIDS and those exposed to the risk of HIV infection.'*

52 Kenya National Strategy for the Prevention and control of non-communicable diseases, 2015-2020, 31.

53 As above, 42 and 61.

54 As above.

55 Act No 14 of 2006.

Public Health Act

The Public Health Act[56] deals with many infectious diseases, including tuberculosis. Section 34 of the Act provides for the power to provide temporary supply of medicines as follows: *'Any municipal council may, with the sanction of the board, themselves provide or contract with any person to provide a temporary supply of medicine and medical assistance for the poorer inhabitants of their district, but may at their discretion charge for the same.'*

This provision may be used to exploit the flexibility of compulsory licenses in the interest of public health. In practice, however, Section 34 of the Public Health Act has never been used in Kenya. There is need to update this Act in line with the constitutional right to health in Kenya.

Cancer Prevention and Control Act

Also relevant is the Cancer Prevention and Control Act,[57] which is '[a]n Act of Parliament to provide for the prevention, treatment and control of cancer and for connected purposes. This Act has no provision to facilitate affordability of medicines and treatment services. In this regard, the Act is deficient and needs review to conform to the constitutional right to health in Kenya.

Constitution, 2010

The overall framework for enactment of laws and policies in Kenya is the Constitution, 2010. In 2010, Kenya enacted a new Constitution, which for the first time enshrined, among others, socio-economic rights under its Article 43. The right to health is specifically enshrined under Article 43(1) (a) as follows:

> *'Every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.'*

The right to health is crucial because it is one of the frameworks that may be employed by the Government of Kenya to safeguard access to medicines in the country. In fact, under Article 19(1), the Constitution recognizes the centrality of the Bill of Rights in government policies and provides that 'The Bill of Rights is an integral part of Kenya's democratic state and is the framework for social, economic and cultural policies.' Under Article 19(2), 'The purpose of recognizing and protecting the human rights and fundamental freedoms is to preserve the dignity of individuals and communities and to promote social justice and the realization of the potential of all human beings.'

56 Chapter 242.

57 Chapter 246B.

The Public Health Act (Kenya): 'Any municipal council may, with the sanction of the board, themselves provide or contract with any person to provide a temporary supply of medicine and medical assistance for the poorer inhabitants of their district, but may at their discretion charge for the same.'

In Article 2(6), the Constitution recognizes international treaties ratified by Kenya as forming part of Kenya's laws. Hence, international norms on the right to health as developed both internationally and regionally under the International Convention on Economic, Social and Cultural Rights (ICESCR) and the African Charter on Human and Peoples' Rights (African Charter) respectively, are also relevant in Kenya. Consequently, in 2008, the African Commission on Human and Peoples' Rights (ACHPR) adopted Resolution 141 on access to health and medicines in Africa urging states to 'refrain from measures that negatively affect access, such as implementing IP policies that do not take full advantage of all TRIPs flexibilities that promote access to affordable medicines, including entering 'TRIPs-plus" free trade agreements.' Similarly, in 2014, the Human Rights Council (HRC) Resolution 23/14 also urged states to 'use, to the full of the provisions of the [TRIPs] Agreement which provide flexibility.'

Following the incorporation of the right to health in the Constitution, 2010, many local non-governmental organizations (NGOs) including Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN) have used the provision to litigate many human rights cases.[58] Indeed, the right to health has been employed to defeat TRIPs-plus provisions in *P.A.O & 2 Others v The AG & 2 Others* in relation to the Anti-Counterfeit Act, 2008. The constitutional right to health is therefore effective in safeguarding access to medicines in Kenya. The right to health also means that Government has an obligation to make use of the TRIPs flexibilities in order to enhance access to medicines in the country.[59]

58 For a complete list of cases litigated by KELIN, see http://kelin.kelinkenya.org/index.php/case-tracker/

59 Katrina Perehudoff K. &Ellen t'Hoen 'Human rights & intellectual property for universal access to new essential medicines' in Z.aheer Babar (ed) *Equitable Access to High-Cost Pharmaceuticals* (2018) Elsevier.

Lastly, the Constitution also protects IPRs under the Bill of Rights. Article 40(5) provides that 'The State shall support, promote and protect the intellectual property rights of the people of Kenya.' Whereas this provision requires the state to protect IPRs, it does not in any way restrict its responsibility to protect the right to health including via the full use of TRIPs flexibilities and other measures.

Health Act 2017

The Health Act No. 21 of 2017 is an Act of Parliament 'to establish a unified health system, to coordinate the interrelationship between the national government and county government health systems, to provide for regulation of health care services and health care service providers, health products and health technologies and for connected purposes.' Section 4(a) of the Act provides that it is a fundamental duty of the State to observe, respect, protect, promote and fulfill the right to the highest attainable standard of health, including reproductive health care and emergency medical treatment by among others developing policies, laws and other measures necessary to protect, promote, improve and maintain the health and well-being of every person. The above provision means that Government of Kenya should not put in place laws and policies that may undermine access to medicines since this will be in violation of the right to health.

The Industrial Property Act, 2001

The Industrial Property Act, 2001 is the main legislation implementing the TRIPs Agreement. Apart from protecting inventions, the legislation also provides for the following TRIPs flexibilities which are important for safeguarding access to medicines.

i) *Compulsory licenses, government use order and voluntary licenses*

Compulsory licensing is provided for under sections 72 to 78 of the Industrial Property Act, 2001.

Industrial Property Act, 2001

Compulsory licenses for nonworking and similar reasons

72. (1) At any time after four years from the filing date of an application or three years from the grant of a patent, whichever period last expires, any person may apply to the Tribunal for a license to exploit the patented invention on the grounds that a market for the patented invention is not being supplied on reasonable terms in Kenya. (2) Notwithstanding subsection (1), a non-voluntary license shall not be granted if the owner of the patent satisfies the Tribunal that circumstances exist which justify the fact that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Kenya.

Compulsory licenses based upon interdependence of patents

73. (1) Where a patented invention cannot be worked without infringing the rights derived from an earlier patent, the owner of the latter patent may request the Tribunal at any time for the grant of a compulsory license with respect to the earlier patent to the extent necessary for the working of his invention, if the invention constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent. (2) The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent. (3) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent. (4) In this section, "earlier patent" or "first patent" means a patent granted on an earlier application or benefiting from an earlier validly claimed priority date, and "latter patent" or "second patent" shall be construed accordingly.

Pre-condition for grants of compulsory licenses

74. (1) A compulsory license shall not be granted unless the person grant of requesting the license:¬

requesting the license:¬ (a) satisfies the Tribunal that he has asked the owner of the patent for a contractual license but has been unable to obtain the license on reasonable commercial terms and within a reasonable time; and (b) offers guarantees satisfactory to the Tribunal to work the relevant invention sufficiently to remedy the deficiencies or to satisfy the requirements which gave rise to his request. (2) the requirement under subsection (1)(a) shall be waived in the case of a national emergency or other circumstances of extreme urgency, provided the owner of the patent shall be so notified as soon as is reasonably practicable.

Grant and term of compulsory licenses

75. (1) In considering a request for a compulsory license, the Tribunal shall decide whether a compulsory license may be granted and shall then, if it decides in favor of the grant taking into account any terms agreed by the parties, proceed to fix the terms which shall be deemed to constitute a valid contract between the parties and shall be governed by the provisions of contractual licenses.

(2) In fixing the terms under subsection (1), the Tribunal shall ensure that the compulsory license: ¬ (a) is limited, in scope and duration, to the purpose for which it was authorized, and the case of semi-conductor technology, shall only be for public non-commercial use or remedy a practice determined after a judicial or administrative process to be anti-competitive; (b) is limited predominantly for the supply of the domestic market; (c) does not entitle the licensee to grant further licenses, without the consent of the owner of the patent; (d) is non-exclusive; and (e) provides for the payment to the owner of the patent of remuneration which is equitable with due regard to all the circumstances of the case, including the economic value of the license. (3) A representative of the Institute and of the Government shall have the right to appear and be heard at the hearing of an application for compulsory license, before the Tribunal.

Kenya is yet to exploit this flexibility, which has been effective in improving access to medicines in Malaysia, Brazil, Thailand and other countries. The use of compulsory licenses has been frustrated by the complex and elaborate preconditions set out in legislation.[60]

Government use orders are dealt with under section 80, 'Exploitation of the patented inventions by the Government or by third persons authorized by the Government or government use'.[61]

Big Pharma has frustrated Government use in Kenya. An application from Cosmos prompted the patent holders of an ARV, Glaxo SmithKline (GSK) and Boehringer Ingelheim, to grant the company a voluntary license[62], and then to cut the prices of their medicines in Kenya[63], thereby effectively ending government's intentions to use this flexibility.

Compulsory licensing for local production of generic medicines may not be feasible in Kenya because of the small size of the market. Currently, reports indicate local producers of ARVs are operating below capacity and supply only about 3% of the market.[64] Cosmos' experience in particular, has discouraged other potential local manufacturers of ARVs. Universal Pharmacy (K) Limited has for instance, shelved its plans to manufacture drugs in Kenya even after negotiating a similar voluntary license.[65]

Kenya's Industrial Property Act, 2001 (Sec.54) allows generic producers to begin to produce their generic versions before a patent expires for purposes of marketing approval.

ii) *Parallel importation and exhaustion of rights*

International exhaustion of rights allows for importation of patented medicines from other markets where medicines have legitimately available at a lower price. Section 58(2) of the IPA, 2001 provides:

> *'The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.'*

iii) *Regulatory review exception or 'Bolar' exceptions*

Section 54(ii) provides for early working or 'Bolar' exceptions, stating that 'The owner of the patent shall have the right to preclude any person from exploiting the protected invention by any of the following acts: (a) when the patent has been granted in respect of a product; (b) sticking such product for the purposes of offering it for sale, selling or using the product.' This means that generic producers can begin to produce their generic versions before a patent expires for purposes of marketing approval. This exception is important in order to facilitate the entry of generic competition into the market upon patent expiry.

iv) *Patentability criteria*

Article 27 of the TRIPs Agreement makes it mandatory for Kenya to recognize and protect all fields of technology, including pharmaceuticals. In this regard, section 22(1) of the IPA, 2001 provides for the protection of new inventions as follows: '[a]n invention is patentable if it is new, involves an inventive step, is industrially applicable or is a new use.' Kenya's patentability criteria are arguably low, meaning that ever-greening of patents is possible in Kenya.

60 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.

61 Section 80(1) of the IPA, 2001 provides for the exploitation of the patented inventions by the Government or by third persons authorized by the Government as follows:
Subject to this section, where:
(a) the public interest, in particular, national security, nutrition, health, environmental conservation, or the development of any other vital sector of the national economy so requires; or
(b) the Managing Director determines that the manner of exploitation of an invention by the owner of the patent or his licensee is not competitive;
the Minister may, upon application to him in the prescribed form and after consultation with the Institute and the owner of the patent, order that the protected invention shall be exploited by a Government Ministry, Department, agency or other person as the Minister may designate in the order, subject to the payment of adequate compensation to the owner of the patent in accordance with this section.

62 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 (accessed 6 October 2018).

63 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.

64 Osewe P.L., Nkrumah Y.K., and Sackey E:'Improving access to medicines in Africa: Assessment of Trade-Related Aspects of Intellectual Property Rights (TRIPs) Flexibilities utilization' (2008) 35 *World Bank.*

65 Osewe P.L., Nkrumah Y.K., and Sackey E:'Improving access to medicines in Africa: Assessment of Trade-Related Aspects of Intellectual Property Rights (TRIPs) Flexibilities utilization' (2008) 35 *World Bank*

Trademark Act

The Trademark Act[66] of Kenya is silent about parallel importation. This has presented enormous challenges for parallel importers, as trademark holders have used it to challenge import of branded medicines.[67] In one case[68], an importer and distributor of Budercort, an inhaler for asthmatic patients, failed to secure a tender to supply the product to Kenyatta National Hospital and unsuccessfully sought to prevent the defendant from using the Budercort trademark. In another case[69], the plaintiff successfully stopped a defendant from marketing a cough expectorant known as 'Tri-histina' after it was adjudged to infringe on a registered trademark 'Trihistamin'. Thus, the Trademark Act has been used to undermine the flexibility of parallel importation.

Competition Act, 2010

The Competition Act[70] seeks to regulate the process of competition in the country in a manner that will protect consumers from unfair and misleading market conduct.[71] However, there are concerns that the policy 'is likely to serve as an adequate corrective intervention for pricing of pharmaceutical products if at all.'[72] Competition law may be used in cases where monopolies abuse their market dominance in order to exploit consumers by charging excessive prices.

In addition, the IP Act, 2001 section 80(1)(b), also empowers 'the Managing Director of KIPI to recommend the issuance of a government use order by the Minister for Trade where the Managing Director determines that the manner of exploitation of an invention by the owner of a patent, or licensee thereof, is not competitive.'[73]

66 Cap 506.

67 Jackline Irene Muthoni Nyaga 'Implementing parallel importation and licensing mechanisms to increase access to medicines in Kenya (2009) 149, fn 156. A thesis submitted to the Stanford program in international legal studies at the Stanford Law School, Stanford University in partial fulfillment of requirements for the degree of Masters of the Science of Law.

68 *Lords Healthcare Limited v Salama Pharmaceuticals Limited (2006)*. High Court of Kenya, Nairobi (Milimani Commercial Courts), Civil Suit No. 334 of 2007. [2008]eKLR

69 *Pharmaceutical Manufacturing Co v Novelty Manufacturing Limited*. [2001] KLR 92.

70 No. 12 of 2010.

71 See Part VI Consumer Welfare (sections 55 to 70)

72 Watu Wamae, Joan Kariuki Kungu, Norman Clark and Maureen Mackintosh 'Spotlight on pharmaceutical pricing regulation in Kenya: How much does it really contribute to access? (Working Brief No 2, September 2014) 2.

73 Munyi above, 17.

Section 2 of Kenya's Anti-Counterfeit Act, 2008, which contains a contentious definition of 'counterfeiting' that can be interpreted to include generic medicines, has been uccessfully challenged in court using the constitutional right to health.

Pharmacy and Poisons Act

The Pharmacy and Poisons Act provides for the licensing of manufacture of medicinal substances and the standards for good manufacturing practices but does not provide for TRIPs flexibilities.[74] The Act also empowers police officers to enter and search premises and retain and dispose any goods seized, 'which the officer has reasonable cause to believe to be evidence of the commission of any such offence' under the Act.[75] Ministry of Health and Pharmacy and Poisons Board have recommended the review of the Pharmacy and Poisons Act in order to accommodate the mechanism of parallel importation in line with the relevant IP laws in Kenya and the TRIPS flexibilities.[76]

Anti-Counterfeit Act, 2008

The Anti-Counterfeit Act 2008 had sought to categorize generic medicines as a public safety issue. Tightening IPR rules through the anti-counterfeit laws raised a new kind of challenge for health advocates – a reframing of such measures in terms of public safety, which made it more difficult for opponents to criticize publicly.[77] The general perception has been that generic medicines 'may lead to an influx of counterfeit drugs'.[78]

74 Section 35A and 35B.

75 Section 45. Various offences have been created under the Act at Part IV on miscellaneous provisions including prohibition of misleading advertisements under section 39.

76 As above, 10

77 Hein W., Moon S., & Poku N.K: 'Informal norms in global governance: Human rights, intellectual property rules and access to medicines' (2013) 140 Taylor and Francis

78 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 (accessed 6 October 2018).

This perception has led to the fashioning of anti-counterfeit legislation in a manner that may also target generic medicines. In this regard, section 2 of the Anti-Counterfeit Act contains a contentious definition of 'counterfeiting' that can be interpreted to include generic medicines.[79]

The Anti-Counterfeit Act has been successfully challenged in court using the constitutional right to health.[80] In this case, three persons living with HIV successfully argued that the anti-counterfeiting legislation potentially threatened access to generic ARVs on which they depended. Unfortunately, the subsequent amendments to the Act only focused on further strengthening of the anti-counterfeiting enforcement regime in Kenya by introducing a board and a coordinator or advisory committee and neglecting the real human rights concerns.[81]

Both Kenya's Science, Technology and Innovation Policy and the Science, Technology and Innovation Act focus on the protection of IPR as opposed to access to innovations.

In 2014, the Anti-Counterfeit Act was amended to restrict to the Kenyan territory[82], but another amendment proposed in 2018[83] threatens this step by proposing a new definition of "counterfeit goods" that reads 'goods that are the result of counterfeiting, and includes any means used for purposes of counterfeiting any item that bears an intellectual property right.' This means that the territorial restriction will be defeated once again.

Science and Technology Act

In 2013, Kenya put in place the Science, Technology and Innovation Act[84] to 'facilitate the promotion, co-ordination and regulation of the progress of science, technology and innovation of the country; to assign priority to the development of science, technology and innovation; to entrench science, technology and innovation into the national production system and for connected purposes.' Like the policy, the law focuses more on the protection as opposed to access to innovations.

79 Section 2 provides as follows: counterfeiting" means taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya or elsewhere in respect of protected goods-
(a) the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;
(b) the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a colorable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his license;
(c) the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author's rights or related rights;
(d) in relation to medicine, the deliberate and fraudulent mislabeling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging; Provided that nothing in this paragraph shall derogate from the existing provisions under the Industrial Property Act.

80 P Ogendi 'Safeguarding access to essential generic medicines in Kenya's Anti-Counterfeit Act: Implementing *PAO & 2Others v AG'* Unpublished LLM thesis, Human Rights and Democratization in Africa, University of Lagos and University of Pretoria, (2012) 52.

81 A Maleche and E Day. 'Right to health encompasses right to access essential generic medicines: challenging the 2008 Anti-Counterfeit Act in Kenya' (December 2014) *2 Health and Human Rights Journal* 101. See also Jacinta Nyachae & Paul Ogendi 'Anti-counterfeiting and access to generic medicines in Kenya' *13(3) Economic and Social Review* (2012).

82 Kenya Gazette Supplement No 75 (National Assembly Bills No. 24).

83 Statute Law (Miscellaneous Amendment) Bill 2018

84 No 28 of 2013.

2.2.3 Kenya's IPR institutional framework

Kenya Industrial Property Institute

The main IP office in Kenya is the Kenya Industrial Property Institute (KIPI) established under section 3 of the Industrial Property Act 2001. One of the functions of KIPI is to 'consider applications for and grant industrial property rights'.[85] KIPI does not have pre-grant opposition procedures meaning that there is need to empower the institution to be able to grant only new inventions for medicines and avoid frivolous patents.[86]

ARIPO

Under Article 59 of the Industrial Property Act 2001, 'A patent, in respect of which Kenya is a designated state, granted by the African Industrial Property Organization (ARIPO) by virtue of the ARIPO Protocol shall have the same effect in Kenya as a patent granted under this Act except where the Managing Director communicates to ARIPO, in respect of the application thereof, a decision in accordance with the provisions of the Protocol that if a patent is granted by ARIPO, that patent shall have no effect in Kenya.' In this regard, the ARIPO is also an important office in IP protection and management in Kenya. Like KIPI, ARIPO does not have pre-grant opposition procedures.

Ministry of Trade

Historically, the process of negotiating the TRIPs Agreement and other WTO agreements has been led by Ministry of Trade. In May 1995, Government of Kenya established an inter-ministerial committee to implement the WTO Agreement.[87] In 1997, the committee was restructured to include representatives from the private sector and civil society and renamed National Committee on WTO (NCWTO), effectively becoming the main engagement body for matters relating to WTO.[88]

The National Committee on WTO (NCWTO), which has representation from relevant government ministries and agencies, the private sector and the civil society, is the main engagement body in Kenya on matters relating to WTO

The TRIPs Agreement sub-committee is chaired jointly by KIPI and Ministry of Trade[89], with the latter doubling as national coordinator and as such, having the responsibility to identify and invite relevant stakeholders into NCWTO.[90] Ministry of Trade also hosts KIPI and the IP tribunal.

Ministry of Health

Ministry of Health is largely responsible for the implementation of the right to health in Kenya. However, its policy and legal framework does not empower the ministry to intervene in matters relating to access to medicines as far as IP issues are concerned.

Anti-Counterfeit Agency

The Anti-Counterfeiting Agency is the main government office responsible for IP enforcement. The Agency is established under section 3 of the Anti-Counterfeit Act 2008. Section 5 of the Act provides that the Agency's function is to 'combat counterfeiting, trade and other dealings in counterfeit goods in Kenya.'

The Judiciary

The judiciary is mainly responsible for dispute resolution. Some decisions such as the *P.A.O & 2Others v. AG & 2Others* have been lauded for being supportive of access to medicines. The constitutional court is thus, crucial in safeguarding the right to health in Kenya.

Civil society

There are numerous civil society organizations (CSOs) and networks working on access to medicines both locally and internationally. The key role the civil society plays is advocacy. There is need for CSOs to counter strategies of private associations, which have been responsible for pushing for more IP protection in Kenya.

85 Section 5(a) of the IPA, 2001.

86 Sangeeta Shashikant 'The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for access to medicines *South Centre, Research Paper 56*(November 2014) x,https://www.southcentre.int/wp-content/uploads/2014/11/RP56_The-ARIPO-Protocol-on-Patents_ENl.pdf (accessed 21 March 2019)

87 Walter Odhiambo, Paul Kamau and Dorothy McCormick 'Kenya's participation in the WTO: Lessons learned' Managing the challenges of WTO participation: Case study 20, https://www.wto.org/english/res_e/booksp_e/casestudies_e/case20_e.htm (accessed 20 October 2018).

88 Walter Odhiambo, Paul Kamau and Dorothy McCormick 'Kenya's participation in the WTO: Lessons learned' Managing the challenges of WTO participation: Case study 20, https://www.wto.org/english/res_e/booksp_e/casestudies_e/case20_e.htm (accessed 20 October 2018).

89 As above.

90 As above.

2.3 Uganda's legal, policy and institutional framework

In this subsection, we review Uganda's legal and policy framework in order to establish the opportunities and gaps on access to medicines in Uganda.

2.3.1 National policies

Vision 2040

Vision 2040[91] aims to transform Uganda from a predominantly peasant and low-income country to a competitive, upper middle-income country. One of the aspirations under the vision is that Ugandans desire to have access to affordable quality health care and in this regard it emphasizes the need to accelerate movement towards universal health care.

Second National Development Plan 2015/16-2019/20

This development plan is the second of the six five-year plans for achieving Vision 2040. Its goal is to propel the country towards a middle-income status by 2020 through strengthening the country's competitiveness for sustainable wealth creation, employment and exclusive growth. The plan is guided by four objectives which include enhancing human capital development and strengthening mechanisms for quality effective and efficient service delivery.

One of its implementation strategies is to integrate key cross-cutting issues such as HIV/AIDS, human rights and social protection into government programs and projects and to mainstream them during implementation, monitoring and evaluation. The development plan speaks of a national policy on medical products and health technologies as having zero tolerance to stock outs of essential medicine and health supplies. It however, acknowledges that most products and technologies are imported due to a low, immature local manufacturing capacity within the country.

The Plan adopts Sustainable Development Goal 3, which is "To ensure healthy lives and promote wellbeing for at all ages". The development plan emphasizes that this necessitates an increase in budget allocation to the health sector.

Second Health Sector Development Plan 2015/16-2019/20

The second Health Sector Development Plan (HSDP II) aims to achieve a healthy and productive population that contributes to socio-economic growth and national development. The strategy is to accelerate movement towards UHC with essential health and health-related services that promote healthy, productive lives for all Ugandans.

91 Available at http://www.gou.go.ug/content/uganda-vision-2040 Accessed on 21/10/2018

Uganda's Second National Development Plan 2015/16-2019/20 targets zero tolerance to stock outs of essential medicine and health supplies, but acknowledges that most products and technologies are imported due to a low, immature local manufacturing capacity within the country

UHC seeks to ensure that all people receive essential and good quality health services they need without suffering financial hardship. The plan is designed to support the SDGs, which target, among others, to "Achieve universal health coverage including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccinations for all" by 2030. The Plan is however, silent on IPR protection could affect the realization of its goals and targets.

Health Sector Strategic Investment Plan

The main objective of the Health Sector Strategic Investment Plan is to implement and harmonize the procurement systems through effective management structures and strong medicine regulatory systems to ensure availability of essential medicines and other supplies. The Investment Plan, however, makes no particular reference to the role of IP in access to medicine or medicines procurement.[92]

National Intellectual Property Policy

The 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 focus of the policy is to promote the use of IPRs to encourage innovation and strengthen URSB. The key elements of the policy are promotion of technology transfer and integration of IP into the health sector.

92 Ellen F. M. 't Hoen et al, 2018. Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region. Journal of Pharmaceutical Policy and Practice volume **11**, Article number: 31 (2018).

National Science, Technology and Innovation Policy and Plan

The National Science, Technology and Innovation Policy 2009 recognizes the low technology capacity of Uganda as reflected by the handful of patents so far granted for local inventions, pointing out that only one or two applications are received per year. The goal of this policy is to strengthen national capability to generate, transfer and apply scientific knowledge, skills and technologies that ensure sustainable utilization of natural resources for the realization of Uganda's development objectives. The policy encourages generation of technology through technological transfer, research and development and use of IP.

On its part, the National Science, Technology and Innovation Plan 2012/13-2017/18 provides the framework for actualizing the policy, through among other strategies, strengthening the legal framework for IP management to encourage scientific innovation. The relevant actions in the plan include a revision of the IP legislation, strengthening of the national IPR office, membership to regional and global organizations dealing with IPR, and incorporating aspects of IPR in the school curricula.

The National Industry Policy 2008

The policy vision is to build the industrial sector into a modern, competitive and dynamic sector fully integrated into the domestic, regional and global economies. The policy encourages innovation and aims to transform Uganda into a modern and industrial nation through innovations and commercialization for technologies.

Of key interest, the policy calls for the promotion of foreign direct investments to bring about technology transfer, among other aspects. This is at the heart of product development and this gives an opportunity of transfer of technology that is a core objective of the TRIPs Agreement[93], which puts emphasis on transfer and dissemination of technology and also creates an obligation for developed nations to provide incentives for technology transfer.

93 TRIPs Agreement, Article 7 states that 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'. And Article 66.2 which provides that 'Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base'.

The National Industry Policy 2008 calls for the promotion of foreign direct investments to bring about technology transfer, which is consistent with the core objective of the TRIPs Agreement

Uganda National HIV and AIDS Policy 2011

The HIV and AIDS policy promotes research and ensures standards, innovation and access to reliable information to attain the overall goal of eliminating the socio-economic impact of HIV and AIDS in the country. The policy also commits to promoting equal access to impact-mitigation services which can be interpreted to mean equal affordable access to ARVs and other treatment interventions, but there are no direct reference to IPR.

National Health Policy 2010

The National Health Policy is guided by the goal of attaining a good standard of health for all people in Uganda in order to promote healthy and productive lives. The focus of the Policy is to ensure universal access to quality Uganda National Minimum Health Care Package (UNMHCP) consisting of the most cost-effective and acceptable priority health care interventions and services addressing the high disease burden.

The UNMHCP commits to provide services for all prioritized diseases and conditions to all people in Uganda with emphasis to vulnerable populations, such as PLHIV. The policy recognizes the need for cost-effective health care interventions but does not link it to IP or recognize IP implications on the price of medicines.

National Drug Policy

The National Drug Policy aims to ensure that essential, safe, efficacious and cost-effective drugs are made available to the entire population of Uganda.[94] It encourages procurement of locally produced drugs with a view of minimizing drug costs. One of the measures that have been implemented to realize this provision is the provision of a tax incentive for local production. On 1 August 2017, Government of Uganda increased the fee for verification of imported medicines from 2% to 12% on a set of 37 medicines that are locally manufactured.[95]

94 Section 2 ibid

95 Ministry of Health, 2017. Government to support local

National Medicines Policy and Strategy

Akin to the National Drug Policy, the National Medicines Policy and Strategy was developed with the aim of attaining the highest standard of health by ensuring access to, and appropriate use of, good quality, affordable essential medicines and health supplies. Its guiding principles are UHC, equity, efficiency and quality. It seeks to increase efficiency in the utilization of available funds, improve the use of medicines, improve pharmaceutical information systems, increase public financing for essential medicines, as well as private sector participation and engagement in policy implementation. Although there is no outright reference to IP, the policy is focused on promoting access to affordable essential medicine.

2.3.2 National laws

National Constitution

The Constitution is the supreme law of Uganda and provides for a bill of inherent rights. However, it does not expressly stipulate the right to health. Instead, it has a number of health-related provisions. Under the National Objectives and Directive Principles of State Policy (NODPSP) and *Article 8A,* it requires the State to ensure that all Ugandans enjoy access to health services through the provision of basic medical services to the population.[96]

In its national policy objectives, the Constitution imposes a duty on the state in matters of development which is to instigate enactment of legislation and policies that enhance the right of people to equal opportunities in development and that the state shall stimulate agricultural, industrial, *technological and scientific* development by adopting appropriate policies and the enactment enabling legislation.[97] Article 189 read together with the sixth schedule of the constitution provides for functions of the state to include responsibility for copy rights, patents, trademarks and all forms of IP. The state accordingly executes its responsibility through enactment of IP laws and policies to protect and enforce IPRs as well as investment in research to encourage scientific development.

The Patent Act

Uganda enacted its first post-independence patent law, the Patents Act, in 1964. This Act granted a right to a patentee whose patent was registered in the United Kingdom (UK), Uganda former colonial master, to have it registered in Uganda. This provision made patents registered in Uganda appear to be an extension of those registered in the UK.

pharmaceutical manufacturers through implementation of 12% verification fee on selected imported medicines. *Press statement,* 10 July 2017.http://health.go.ug/download/file/fid/1469

96 Constitution of the Republic of Uganda, NODPSP Objectives XIV and XX

97 Objective XI (ii) The Constitution of Uganda 1995

Uganda's Constitution imposes a duty on the state to stimulate agricultural, industrial, technological and scientific development by adopting appropriate policies and the enactment of enabling legislation.

This Act was repealed in 1991, with the enactment of the Patents Statute No.10 of 1991. This statute was later in 2000 renamed during the compilation of the laws of Uganda as the Patent Act Cap 216 of 1993.

In April 1994, a year after enacting the Patents Act of 1993, Uganda signed the agreement establishing WTO. All WTO members were required to put in place by 2005 minimum standards of IPR protection set by the TRIPs Agreement in 1994. The TRIPs Agreement provided for IPR protection in all fields of technology, including pharmaceuticals, and for imported as well as locally-produced commodities.[98]

As an LDC, Uganda qualified for the transition period[99], but it nonetheless had a general obligation to reform national laws and conform to the minimum standards of the TRIPs Agreement.[100] Subsequently, Uganda Law Reform Commission (ULRC) spearheaded[101]a reform of commercial laws, including the Patent Act and to incorporate provisions that conformed to the TRIPs Agreement. These reforms were guided by the Doha Declaration[102] which took cognizance of the public health challenges faced by developing countries and emphasized protection of public health interest above individual interests of patent holders.

In its report, ULRC made several recommendations which led to a repeal of the Patent Act and an enactment of a new Industrial Property Act which came into force in 2014.

98 Article 27 (1) WTO-TRIPS Agreement

99 The first transitional period was granted until 2005 and then extended to 2016 and through further negotiations the waiver on pharmaceutical was extended to 2033

100 Article XIV.4 of the Agreement establishing the WTO Agreement provided that each member state shall ensure its laws and regulations are brought into conformity with its obligation under the Agreement.

101 The review of commercial laws commenced in 2000

102 The Declaration was adopted at the 4thSession of the WTO Ministerial Conference in Doha, Qatar on 14th November, 2001

The Industrial Property Act 2014

The Industrial Property Act is the primary law governing IP in Uganda following the repeal of the Patent Act 1993. The Act provides promotion of inventive and innovative activities, to facilitate the acquisition of technology through the grant and regulation of patents.

The new law extended the term[103] of patents, exempted pharmaceutical patents, provided for government or third party exploitation of patented inventions, enumerated non-patentable inventions,[104] and provides for parallel importation. Hence, the Act incorporates a number of TRIPS flexibilities that can be used to promote access to medicines.

However, like other LDCs, Uganda faces challenges in implementing the TRIPS flexibilities, and several stakeholders, particularly CSOs, raised these challenges to the WTO council at the end of the 2005 transition period.[105] The challenges include limited technical and financial capacities, a weak IP office, and limited IP knowledge among public and private sector actors.

Although the Act provides for windows of opportunity, there has been minimal exploitation of any legal reforms to aid access to affordable medicines since Uganda is still exempted from granting or enforcing patents on pharmaceutical products. However, the transition should be effectively utilized to promote of technological transfer.

103 Extended from 15 years to 20 years in light of Article 33 of the TRIPs Agreement

104 In light of Article 27 (2) and (3) of the TRIPs Agreement.

105 http://www.ip-watch.org/2015/11/06/ldc-pharma-ip-waiver-until-2033-approved-by-wto-trips-council/

Uganda faces challenges in implementing the TRIPS flexibilities due to limited technical and financial capacities, a weak IP office, and limited IP knowledge among public and private sector actors.

Trademark Act 2010

The Trademark Act 2010 is one of the laws that emerged from the legal reform process of 2000. It deals IP that relates to identity of products, brand names, logos and other distinctive signs. Although Uganda does not have a stand-alone competition law, the IPRs under this Act are given to avoid unfair competition by clarifying the identity of different goods.

This law came under the spotlight after the anti-counterfeit bill was proposed with a broad definition of counterfeits that included generic medicines.

Anti-Counterfeit Bill

In 2015, Government of Uganda introduced the anti-counterfeit Bill sparking concerns because of the fear that it was likely to restrict access to generic medicines. The Bill sought to prohibit the manufacture, trade and release of counterfeit products but its definition of counterfeit posed a threat because of its broad nature. Enforcement of anti-counterfeit measures can easily exceed the requirements of the TRIPs flexibilities and hence, TRIPs-plus.

Uganda's Industrial Property Act 2014 incorporates the following TRIPS flexibilities

a) **Transition period**: With the exemption granted to LDCs, the Industrial Property Act excludes pharmaceutical products and test data from being patented[1] until 1 January 2016 or such period[2] as maybe granted by the TRIPs Council. To enforce this provision, the Industrial Property Regulations 2017 were passed and accordingly exempt[3] the application of the regulations to pharmaceutical products, categorically stating that the registrar shall not accept an application to register a patent, utility model, industrial design or microbiological products or processes for producing pharmaceutical products until the expiry of the transition period granted to LDCs under the TRIPS Agreement.

a) **Patentability criteria:** The Act also provides for a patentability criteria that requires novelty[4]; an invention not be anticipated by prior art which is described to include anything made available to the public around the world by written or oral disclosure before the filing of the application.[5] The invention also ought to involve an inventive step which ought to not have been anticipated by prior art basing on the test of obviousness[6] and it ought to be industrially applicable by being capable of being used in any kind of industry[7], including medicine.

b) **Compulsory licensing** (s.66) allows Government use of a patent through compulsory licensing where there is public interest, including health.

c) Post-grant opposition which both offer an opportunity to disqualify undeserving patents that may affect access to essential medicine. However, the process of opposition is lengthy and requires technical knowledge.

d) Section 8(3)(f) exempts pharmaceutical products from patenting during the LDC waiver.[8]

e) Section 44 allows the use of patented invention without authorization for experimental research including use of clinical data as long as they acquire approval from National Drug Authority (NDA).

2.3.3 Institutional framework

Uganda Registration Services Bureau

The Uganda Registration Services Bureau (URSB) is a statutory body with the mandate to administer IPR. The body promotes IP protection through registration of patents, copy rights, trademarks and other related IPRs. The mandate of URSB also extends to formulation of IP laws, provision of advice to government on IP issues, and providing a link to ARIPO and WIPO.

URSB is now a fully-fledged national IP office with registrars and examiners of patents. Previously, all substantive examinations were done at ARIPO. URSB has been instrumental in the formulation of the draft IP policy and promotion of IP awareness through holding of monthly clinics and quarterly national seminars in partnership with ARIPO and WIPO.

ARIPO

The Harare Protocol on Patents and Industrial Designs[106] empowers ARIPO to grant patents and other IPRs and administer such patents on behalf of member states[107], which include Kenya and Uganda. In line with other international treaties, the Protocol extends the scope of patents to all fields of technology provided they are new, not obvious and with industrial application.[108]

On behalf of 19 member states, ARIPO acts as a custodian of IPR within the African region, but most importantly to promote the interests of its members such as ensuring that no pharmaceutical patents are granted for LDCs in the transitional period.[109]

Ministry of Trade, Industry and Cooperatives

Ministry of Trade, Industry and Cooperatives is responsible for promoting trade, industry and cooperatives for the development of the country. This Ministry is charged with ensuring expansion and diversification of environmentally sustainable industrialization, appropriate technology, conservation and preservation of other tradable national products. These roles are targeted at generating wealth to benefit the country socially and economically.

The Uganda Registration Services Bureau has been instrumental in the formulation of Uganda's Intellectual Property Policy and in the promotion of intellectual property awareness

It has the responsibility to formulate policies, and to plan and coordinate the diversification and improved competitiveness of the industrial and technological sector. Its functions partly focus on promotion of industrial research, science and technology and use of IP in the development of science, technology and innovation (STI).

Ministry of Health

Ministry of Health is the custodian of health services in Uganda and the pharmacy division is charged with the responsibility of managing the pharmaceutical services and providing oversight for the National Medicines Policy. The objectives of this division include quantifying requirements of pharmaceutical products, harmonizing the supply chain management system, promoting rational use of pharmaceutical products, coordinating pharmaceutical sector performance, and monitoring and evaluation of the pharmaceutical sub-sector.

Under the Pharmacy Division is the Quantification Procurement Planning Unit, which is a centralized system responsible for projecting and quantifying national requirements for essential medicines and health supplies. There are opportunities to utilize parallel importation to ensure that the country imports essential medicines as the fairest prices.

However, the Division has not integrated IP into its supply and procurement chain. The policy document that guides this department, the National Medicines Policy, is also silent about IP and medicine patents.

106 Uganda acceded to the Harare Protocol on 8th August 1978
107 Section 1 of the Harare Protocol
108 Section 3 (10) (a) of the Harare Protocol
109 Shashikant, S.,2014. The African Regional ARIPO Protocol on Patents: Implications for access to medicines, south center. Research Paper 56

National Council for Science, Technology and Innovation

Established by the National Council of Science and Technology Act, the Council's strategic goal is to strengthen the national system of research, product development and technological transfer and IP management. Its main function is to regulate research and development. Others include advising and coordinating the formulation of an explicit national policy on all STI fields and promoting indigenous STI through research, technological transfer and adaptation and innovation, among others.

National Drug Authority

Established by the National Drug Authority Act, NDA is a key player in ensuring access to medicine. Its functions include: dealing with the development and regulation of the pharmacies and drugs in the country; controlling the importation and exportation and sale of pharmaceuticals; control of the quality of drugs; promoting and controlling local production of medicines; encouragement of research and development of herbal medicine; and promoting rational use of drugs. NDA regulates the importation, manufacture, sale and prescription of medicines and medical supplies in Uganda. It also regulates clinical research in medicines, and as such, has the potential to enhance the utilization of TRIPs flexibilities, particularly parallel importation and promotion of local manufacturing.

Uganda Industrial Research Institute

Uganda Industrial Research Institute (UIRI) was established by an Act of Parliament in 2002, with a vision to be a center of excellence for incubation of industry and undertaking industrial research and development to elevate the level of technology in Uganda and the region.

The National Council of Science and Technology has the mandate to strengthen the national system of research, product development and technological transfer and IP management.

UIRI's mission is to improve the capacity and competence of indigenous entrepreneurs in undertaking viable industrial production processes and to provide demand driven scientific and industrial research and development to facilitate rapid industrialization. As a research institution, UIRI is a potential consumer of IP services, particularly of patent protection.

A review of relevant national policies also indicates that there is no consensus on the importance or implication of excessive IPR protection on access to medicines. In Uganda, key policies like the National Health Policy II, the HIV/AIDS Policy, the National Medicines Policy, National Drug policy do not highlight IPRs or make reference to the use of TRIPS flexibilities.

3. Patent Status of Selected Medicines for HIV, TB, NCD and HCV

This section covers patent information of medicines for HIV, opportunistic infections, TB, NCDs and HCV; medicine international reference prices; and emerging issues.

A patent is the right given to an inventor to prohibit others from using their invention without consent of the patent holder. Patents are valid for a specified period of time, during which they are used to ban and delay competition from competitors, who in the case of medicines are usually generic manufacturers. Competition is normally only possible through the consent of the patent holder who agrees to issue voluntary licenses to other manufacturers under preset or negotiated terms. Kenya and Uganda are among the beneficiaries generic ARVs produced under MPP licenses. Otherwise, the only other way competition is possible is through the exploitation of TRIPs flexibilities, particularly compulsory licenses.

It is important to note that the base/compound patent is generally the strongest patent. As long as the compound patent is not expired, generic competition is difficult without either a compulsory or voluntary license.

3.1 Number of patents on ARVs

In Kenya, out of 140 possible patents on 21 ARV products, 23 patents had been granted and still valid. Manufacturers of ARVs had not filed for 47 patents and 70 patents had expired by the time of the study. On the other hand, out of 116 possible patents on 19 ARVs in Uganda, 16 had been granted and were still valid; 42 had not been filed; and 58 had expired. A number of patents expired between 2016 and 2018 in Kenya (41%) and Uganda (50%).

Table 1 shows specific information on the number of patents not filed, expired and granted. Details of description of each of the patents including patent numbers and expiry dates are shown in the Annex section.

Table 1: Number of ARV patents

Name of medicine	Not filed		Expired		Granted	
	Kenya	Uganda	Kenya	Uganda	Kenya	Uganda
Dolutegravir	2	3				
Dolutegravir/Rilpivirine	1	1			4	4
Nevirapine			6	8		
Tenofovir/Lamivudine+Nevirapine	2	2	2	2		
Zidovudine			2	3		
Efavirenz/Lamivudine/Tenofovir	2	2				
Dolutegravir/Lamivudine/Tenofovir	3	3				
Lamivudine/Zidovudine			6	6		
Efavirenz	1	5				
Tenofovir/Emtricitabine/Efavirenz	6	4	1	1	1	1
Abacavir			16	12	1	1
Abacavir/Dolutegravir/Lamivudine	1	1	8	8	1	
Abacavir/Lamivudine			18	9		
Abacavir/Lamivudine/Zidovudine			11	9		
Darunavir	13	13			7	7
Duranavir/ Cobicistat	1	_				
Duranavir/ Cobicistat/Emtricitabine					6	_
Atazanavir/Ritonavir	5	3				
Lopinavir/Ritonavir	4	3				
Raltegravir	6	2				
Etravirine					3	3
Total	**47**	**42**	**70**	**58**	**23**	**16**

3.2 Patent information

3.2.1 Antiretroviral medicines

In Kenya, the preferred first line regimen for adults and adolescents aged 10 years or more and weighing at least 35kg is Tenofovir, Lamivudine and Efavirenz or Nevirapine (TDF+3TC+EFV or NVP); or Zidovudine (AZT), 3TC and EFV or NVP. In Uganda, the preferred first line regimen is Tenofovir, Lamivudine and Dolutegravir (TDF+3TC+DTG) and two recommended alternative regimens, TDF+3TC+EFV and ABC+3TC+DTG. These regimens contain a total of seven medicines, of which four (ABC, AZT, NVP and 3TC) have expired patents. The rest of the medicines – Tenofovir, Efavirenz and Dolutegravir have not filed for patents in Uganda. In Kenya, EFV and TDF have no filed patents but there is a mixed picture for DTG which has no patent filed for most combinations except one with Rilpirivirine.

The preferred regimen for adult women and adolescent girls of child-bearing potential who are pregnant, intend to get pregnant or are not on effective contraception – TDF+3TC+EFV – and the recommended alternatives (TDF+3TC+ATVr and ABC+3TC+EFV) have a total of five medicines, of which two (ABC and 3TC) have expired patents. Tenofovir and Efavirenz have not filed for patents. The combination of Ritonavir-boosted Atanazavir did not have a filed patent and as separate drugs, Atanazavir and Ritonavir have not filed for patents in Uganda. For Kenya, AZT-based combinations are preferred.

The preferred regimen for children of less than three months – ABC+3TC+LPV/r (syrup) – and the recommended alternative regimen (ABC+3TC+RAL) contain a total of five medicines, of which two medicines (ABC and 3TC) have expired patents. The patents of the other three medicines, including Raltegravir, Lopinavir and Ritonavir as well as for the pediatric formulation of fixed dose Ritonavir-boosted Lopinavir (LPVr 80mg/20ml), have not been filed.

The preferred regimen for children 3 months to three years – ABC+3TC+LPV/r (pellets) – and the recommended alternative regimen (ABC+3TC+RAL) have a total of five medicines, of which two medicines (ABC and 3TC) have expired patents. The patents of the rest of the medicines, including Raltegravir, Lopinavir and Ritonavir, have not been filed.

The preferred regimen for children between 3-10 years – ABC+3TC+LPV/r (tablets) for both countries. The recommended alternative regimens for Uganda are (ABC+3TC+DTG and ABC+3TC+RAL) while for Kenya (AZT+3TC+LPV/r). This is a total of seven medicines, of which patents have expired patents or not been filed.

The two recommended regimens for HIV pre-exposure prophylaxis (PrEP) in Uganda are TDF 300mg+FTC 200mg and TDF 300mg+3TC 300mg – have a total of three medicines. The patent for one of the regimens (TDF/FTC) fixed dose has been patented until 2024, even though the patent for Tenofovir alone has not been filed. The status of Emtricitabine (FTC) could not be traced in the database. The patent for the combination that makes the second regimen (TDF 300mg+3TC 300mg) has not been filed. For Kenya, the recommended regimen for PrEP is TDF 300mg+FTC 200mg which is patented until 2024.

In Uganda, the two recommended adult regimens for HIV post-exposure prophylaxis (PEP) are TDF+3TC+DTG and TDF+3TC+ATVr. In Kenya, it is TDF/AZT+3TC+LPV/r. This makes a total of seven medicines, of which patents have either expired or not been filed.

The two recommended pediatric regimens for PEP – ABC+3TC+LPVr and ABC+3TC+DTG – have a total of five medicines, of which two medicines (ABC and 3TC) have expired patents, while the rest have not filed for patents.

In Uganda, Zidovudine and Nevirapine, which may be substituted for some medicines in the preferred first line regimens to generate second line regimens, have expired patents. For Kenya, AZT and TDF substitute each other as well as Stavudine (d4T) to form second line in combination with Ritonavir-boosted protease inhibitors. Patents for Ritonavir-boosted protease inhibitors, which are also key in second line treatment, have not been filed or are expired (in the case of Kenya). However, novel medicines such as Etravirine and Darunavir, for third line regimens, are patented in Uganda. Raltegravir is one of the very few newer medicines for which a patent application has not been filed in either of the countries.

Lamivudine was not patented while the patent for AZT expired in 2016. The combination of the two (3TC/AZT) was patented until 2017.

Patents for Ritonavir-boosted protease inhibitors, which are also key in second line treatment, have not been filed or are expired (in the case of Kenya). However, novel medicines such as Etravirine and Darunavir, for third line regimens, are patented in Uganda.

3.2.2 Medicines for opportunistic infections

The key medicines for opportunistic infections are Fluconazole and Cotrimoxazole. Cotrimoxazole is also used for prophylaxis of opportunistic infections in persons living with HIV. Both these medicines are old and off-patent.

3.2.3 Medicines for TB

The medicines for first line treatment of TB include Isoniazid, Rifampicin, Pyrazinamide, Ethambutol and Streptomycin, all of which are not on patent.

The medicines for the treatment of multi-drug resistant TB (MDR) include Capreomycin, Kanamycin, Cycloserine, Ethionamide, Levofloxacin, Amikacin and Moxifloxacin. Of these medicines, only Moxifloxacin is on patent, but it has not been filed in Uganda.

Medicines for treatment of Extensively Drug-Resistant (XDR) TB include Bedaquiline, Clofazimine and Linezolid. Of these, Bedaquiline has patents running until 2027.

Only two medicines (Ribavarin and Velpatasvir) for Hepatitis C are off-patent and one other (Daclatasvir) has not been filed.

Table 2: Patent status of XDR TB medicines

Generic name	Strength	Patent description	Kenya/Uganda expiry date	Patent status
Bedaquiline	100 mg	Bedaquiline compounds family	18/07/2023	Granted
		Bedaquiline to treat MDR TB	24/05/2025	Granted
		Bedaquiline to treat latent TB	12/08/2025	Granted
		Bedaquiline fumarate salt	12/03/2027	Granted
Clofazimine	100 mg			
Linezolid	600 mg			

3.2.4 Anticancer medicines

The Uganda Clinical Guidelines 2016 has over 40 medicines for treatment of cancer, including Anastrozole, Bleomycin, Docetaxel and Rituximab. All the 40 medicines are not patented.

3.2.5 Medicines for Hepatitis C

The existing medicines for Hepatitis C treatment are highly patented. Only two medicines (Ribavarin and Velpatasvir) are off-patent and one other (Daclatasvir) has not been filed. One key medicine for treatment of Hepatitis C, Sofosbuvir, and all its combinations – Sofosbuvir+Daclatasvir, Sofosbuvir+Velpatasvir, Sofosbuvir+ledipasvir, and Sofosbuvir+Velpatasvir+Voxilaprevir – are all patented.

4. Links between Patent Status and Prices

4.1 Patent status and medicine prices

Patent status was compared to international supplier prices of selected medicines for HIV, XDR TB and Hepatitis C. The fixed dose combination of Efavirenz/Lamivudine/Tenofovir was the cheapest ARV regimen. ARV prices increased with newer medicines or those used as second line (Atazanavir/Ritonavir, Lopinavir/Ritonavir) and third line (Raltegravir, Etravirine). Although a patent had not been filed for Raltegravir, the price of 60 tablets of the medicine (USD 52.13) was higher than that of a pack of 112 tablets of Etravirine at USD 37.98. For XDR TB, a dose of the preferred medicine, Bedaquiline, costs USD 3000. The price of patented newer treatments for Hepatitis C was very high.

ARV prices increased with newer medicines or those used as second line (Atazanavir/Ritonavir, Lopinavir/Ritonavir) and third line (Raltegravir, Etravirine)

Table 3: Patent and medicine prices

Generic name	Strength	Kenya expiry date	Patent status in Kenya	Uganda expiry date	Patent status in Uganda	Package	International supplier price (USD)
ARV Formulations							
Efavirenz/Lamivudine/Tenofovir	600/300/300	-	Not filed	-	Not filed	30 tab	9.78
Tenofovir/Emtricitabine/Efavirenz	300/200/600 mg	13/01/2024	Filed	-	Not filed	30 tab-cap	10.66
Abacavir	300 mg	14/10/2018	Expired	14/10/2018	Expired	60 tab-cap	12.18
Abacavir/Lamivudine	600/300 mg	14/10/2018	Expired	14/10/2018	Expired	30 tab-cap	14.2
Abacavir/Lamivudine/Zidovudine	300/150/300 mg	14/10/2018	Expired	14/10/2018	Expired	60 tab-cap	23.45
Darunavir	600 mg	-	Not filed	-	Not filed	60 tab-cap	54.81
Atazanavir/Ritonavir	300/100 mg	-	Not filed	-	Not filed	30 tab-cap	19.27
Lopinavir/Ritonavir	200mg/50mg	-	Not filed	-	Not filed	120 tab-cap	19.68
Raltegravir	400mg	-	Not Filed	-	Not filed	60 tab-cap	52.13
Etravirine	200mg, 100mg & 25 mg	11/04/2019	Granted	11/04/2019	Granted	112 tab-cap	37.98
TB-XDR medicine							
Bedaquiline	100 mg	12/03/2027	Granted	12/03/2027	Granted	100 tab-cap	3000
Clofazimine	100 mg	-	-	-	-	100 tab-cap	126.72
Hepatitis C treatment							
Ribavarin	200mg	-	-	-	-	42 tab-cap	12.28
Daclatasvir	60 mg	-	Not filed	-	Not Filed	84 tab-cap	63,000
Sofosbuvir+Daclatasvir	400+60 mg	27/11/2032	Filed	31/03/2031	Granted		147,000
Sofosbuvir	400 mg	27/11/2031	Granted	27/11/2032	Filed	84 tab-cap	84,000
Sofosbuvir/Ledipasvir	400/90 mg	30/01/2034	Filed	30/01/2034	Filed	84 tab-cap	94,500

Source: http://www.medspal.org; http://mshpriceguide.org/en/drug-search-page-2/.

4.2 Key advocacy issues emerging from the analysis of patent status

- It is apparent that while Uganda is an LDC with policy space not to grant patents, it continues to grant patents on key medicines. It was reported that ARIPO which files patents on behalf of the countries, does not notify patent offices in the countries. It is important that there is a communication link between ARIPO and country patent office so that for example Uganda takes benefit of the policy space.
- Each medicine had on average seven different patents in Kenya and six in Uganda, based on the strengths; salts used for the compound; manufacturing process; use; or the combination in which it was provided with other medicines. Each of these different modifications had either the same or different patent expiry dates.
- Kenya is using older ARVs compared to Uganda. This may be attributed to the patent regime, where Kenya as a middle-income country is required to implement the TRIPs Agreement whereas Uganda as an LDC is exempted until 2033. It is important that both countries take advantage of the opportunities provided by the MPP.
- Besides Bedaquiline and Moxifloxacin, the rest of the medicines for TB are very old and off-patent and the same applies to anti-cancers.
- Although a patent had not been filed for some medicines, the price was in some instances higher than that of medicines that were on patent (e.g. RAL v. ETV).
- Older first line ARVs are being replaced by newer, safer medicines which are more expensive.
- Some of the newer medicines for which patents have not been filed are available in combinations that are patented.

5. Emerging Issues, Opportunities and Challenges

5.1 Opportunities

The legal framework for the utilization of TRIPS flexibilities is in place at the EAC level, as well as at the national level in Kenya and in Uganda. The EAC Regional Intellectual Property Policy on the utilization of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, 2013[110] and the second EAC Regional Pharmaceutical Manufacturing Plan of Action (2017-2027) are crucial policy documents on access to medicines in the two countries.[111]Both Kenya's Intellectual Property Act (2001) and Uganda's Industrial Property Act (2014) have incorporated TRIPS flexibilities. Study respondents cited these laws as constituting a positive legal framework that presents an opportunity for the utilization of the TRIPS Agreement.

Respondents also cited the existence of the requisite institutional framework to promote and regulate research. In Uganda, respondents cited Uganda National Health Research Organization (UNHRO), which is supposed to guide the health research agenda in the country.

There has been an effort in Kenya and Uganda to manufacture generic antiretroviral drugs 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 generic antiretroviral as well as anti-hypertensive, anti-diabetic, anti-ulcerant and anti-Parkinson medicines, 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. Most local manufacturers are producing below maximum capacity, have room for expansion and can bring down prices with economies of scale if governments can expand local procurement.

Besides local production, there are many producers of generic medicines globally from which countries with limited local production capacity such as Kenya and Uganda can import from under the parallel importation TRIPS flexibility. Previously, India dominated the production and export of generic medicines, but more recently generics are also coming from Israel, US and Europe.

Both Kenya's Intellectual Property Act (2001) and Uganda's Industrial Property Act (2014) have incorporated TRIPS flexibilities; both countries have the requisite institutional framework to promote and regulate research; and there have been efforts to manufacture generic medicines in both countries

Parallel importation is possible but the national laws in Kenya and Uganda have to explicitly allow importation of such generics put legitimately on the market in the exporting market. Under Article 31 of the TRIPS agreement, Uganda and Kenya can also ask exporting countries to issue a compulsory license to produce and export under this mechanism.

R&D is currently ongoing in the country at KEMRI, universities and ACTS in Kenya, and at Makerere University, Uganda Virus Research Institute, Baylor University Children's Foundation and TASO in Uganda. While most of the R&D in Kenya and Uganda is foreign driven, the research institutions have over time built research capacity, including among local researchers, which national governments can build on to launch locally driven national research agenda.

There is high prevalence and use of traditional medicine in Uganda and Kenya. More than 70% of the population in Kenya and more than 60% in Uganda depend on traditional medicine for many reasons. In Uganda, and there are initiatives such as THETA and the Natural Chemotherapeutics Research Laboratory (NRCL) that are focused on promoting herbal medicine to promote and restore health.

Ministry of Health has drafted a policy on Traditional and Complementary Medicine to guide the practice of traditional medicine, R&D and the protection, cultivation, propagation and sustainability of traditional medicinal plants. A Bill has proposed the establishment of a semi-autonomous body, the National Council of Indigenous and Complementary Medicine Practitioners, to support collaboration between the "modern" health sector and traditional practitioners and to regulate the latter, while protecting their intellectual property rights.

110 http://eacgermany.org/wp-content/uploads/2014/10/EAC-TRIPS-Policy.pdf (accessed 23 October 2018).

111 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action (2017-2027) 30, http://eacgermany.org/wp-content/uploads/2018/04/2nd-EAC-Regional-Pharmaceutical-Manufacturing-Plan-of-Action-2017%E2%80%932027.pdf (accessed 23 October 2010).

In Kenya, the National Policy on Traditional Medicine and Medicinal Plants aims to achieve conservation of medicinal plants, equitable sharing of benefits, and enhancing production and domestication, while ensuring the safety and efficacy of the products. It will also give guidance to practitioners, consumers and regulators. However, the Industrial Property Act, which could protect the IPR of traditional practitioners, disqualifies traditional knowledge, exposing medicinal plants to indiscriminate exploitation and bio-piracy.

There are positive policy initiatives to support investment in local pharmaceutical manufacturing in at the regional level.

The EAC Regional Pharmaceutical Manufacturing Plan of Action 2017-2027, the roadmap towards an efficient and effective regional pharmaceutical industry, has set four "high-level" targets: 1) Reversing dependency on pharmaceutical imports from outside EAC from more than 70% to less than 50%; 2) Support the expansion of product portfolio of EAC firms to cater for more than 90% of disease conditions; 3) At least 50% of purchases by EAC national medicines procurement agencies are to be sourced from EAC pharmaceutical manufacturers; and 4) Support local industry in expanding their portfolio.

The Plan targets at least five companies to produce advanced pharmaceutical formulations. Some of the strategies to achieve these targets include: incentive packages (tax, preferential treatment, land allocation, etc.); appropriate financing schemes for upgrade of the sector; preferential pricing; a regional center for production of Chemical Reference Substances; and utilization of TRIPS flexibilities. There is a proposal for EAC to set a common external tariff of 25% on imports of items that are also produced locally.

The Buy Uganda Build Uganda (BUBU) Policy 2014 aims **to** promote the consumption of locally produced goods and services products through public procurement and encouragement of the private sector to consume locally originating products thus increasing the participation of the locally established firms in domestic trade. Pharmaceuticals is one the BUBU priority industries, and for selected items, an import tax of 12% is charged, compared 2% for rest of the items. Local producers are also given a 15% advantage in public procurement.

"I know of a case where a local manufacturer ordered APIs in a country where no patent existed since the patent in Kenya was due to expire in one or two years. This company was followed here in Kenya despite the fact that the APIs were imported into another country (where the patent did not exist) and not into Kenya," – personal interview, key informant, PharmaQ

"The big pharma is doing many things to circumvent the state from using TRIPs flexibilities. The use of donations has proved to be an effective strategy. In Kenyatta hospital for example, cancer medicines are being donated meaning that the procurement process will be interfered with," – personal interview, key informant, Advocate of the High Court of Kenya

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5.2 Challenges

The main challenge being faced is the use of legal threats by big pharma against whoever attempts to exploit their patents. Western giant pharmaceutical companies have put pharmaceutical manufacturers in emerging market on focus. In relation to early working, western pharmaceutical giants are monitoring companies and individuals through the suppliers of raw materials of API. In this regard, if anyone makes an order for APIs which is capable of making a patented product then they follow them up with threats.

Another challenge is big pharma's deliberate sabotage of local pharmaceutical production in developing countries. This is done through interference in the market. Medicine donations are strong tool that big pharma used to undermine local pharmaceutical production in developing countries. In 2004/2005, Cosmos successfully pushed for a compulsory license in order to produce ARVs in Kenya. Boehringer and GSK eventually agreed to give voluntary license but this deal was frustrated because of lack of government tender and Roche subsequently launched a program to provide free medicines to the government, undermining Cosmos' market.

The medicine regulatory framework is fragmented, particularly in Kenya where the Pharmacy and Poisons Board (PPB) and the National Quality Control Laboratory have openly failed to agree on each other's mandates in quality assurance.

Counterfeiting continues to affect the quality of medicines in Uganda and Kenya and this threatens the right to quality medicines in both countries. From an IP perspective however, the war on counterfeiting is turning out to be a threat to access to generic drugs globally,

undermining the abilities of countries to utilize the TRIPS flexibility of parallel importation. There seems to be a mysterious enthusiasm by the state in Kenya and Uganda, as in many developing countries, to enforce the rights of *big pharma* as opposed to those of the citizens to access essential medicines. Local pharmaceutical manufacturers may not invest in production of generic medicines if the state itself remains the threat.

Another challenge is the common practice of "ever-greening" of patents through patenting of different compounds with basically the same molecules or active ingredient. This is largely facilitated by lax patentability criteria and patent examination.

The cost of setting up pharmaceutical manufacturing plants is high generally high safety standards and expensive technology. The TRIPS transition period has not effectively supported technology transfer in the pharmaceutical industry. Respondents in this study indicated that investing in pharmaceutical manufacturing in developing countries is not profitable due to high technology and production costs.

6. Conclusions and Recommendations

1) Institutional collaboration should be strengthened, particularly between the Ministries of Health, the IP office and regulatory institutions to protect and promote access to medicines as well as ensuring policy coherence

2) Kenya and Uganda should explore regional cooperation which provides ample options to deal with patent barriers. The EAC, being a regional bloc with over 50% members being LDCs, can make use of the regional exception, a TRIPS flexibility that facilitates the production or procurement of generic medicines to the benefit of the entire region.

3) The governments of Kenya and Uganda, as well as the EAC should ensure that anti-counterfeit legislation do not hamper legitimate trade in generic medicines.

4) Since the Medicines Patent Pool has expanded its mandate to all other diseases, patent holders and those involved in the development of new medicines should commit to licensing for low and middle income countries.

5) Governments should sensitize policy makers, legislators and other decision makers at different levels for them to appreciate the value of quality assured generic medicines and their important role to protect the rights of citizens to have to access affordable, quality health goods and services.

6) Uganda, as an LDC, should not grant or enforce patents on pharmaceutical products at all.

7) CSOs should continue to advocate for, and engage policymakers on the full utilization of TRIPS flexibilities in the response to not only the infectious diseases such as HIV and TB, but also to emerging ones, such as NCDs.

Annexes

Annex I: Medicine and patent and price information for Uganda

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Dolutegravir										
	10mg	Dolutegravir compound	MPP license on pediatric formulation of DTG				Not Filed			
	25mg	Dolutegravir compound	MPP license on pediatric formulation of DTG				Not Filed			
	50gm	Dolutegravir compound	MPP license of adult formulation of DTG & MPP license on peadiatric formulation of DTG				Not Filed			
Dolutegravir/ Rilpivirine	50/25 mg									
		Rilpivirine compound & combinations	Bilateral license on RPV	AP200402993	HIV Replication Inhibiting Pyrimidines	08/09/2022	Granted			
		Rilpivirine compound & combinations	Bilateral license on RPV	AP200603551	Combinations Of A Pyrimidine Containing Nnrti With Rt Inhibitors	09/03/2024	Granted			
		Rilpivirine compound & combinations	Bilateral license on RPV	AP200703933	Fumarate Of 4 [[4 [[4 (2 Cyanoethenyl) 2,6 Dimethylphenyl] Amino] 2 Pyrimidinyl]Amino]Benzonitrile	09/02/2025	Granted			
		Rilpivirine compound & combinations	Bilateral license on RPV	AP200703934	Hydrochloride Of 4 [[4 [[4 (2 Cyanoethenyl) 2,6 Dimethylphenyl]Amino] 2 Pyrimidinyl]Amino]Benzonitrile.	09/02/2025	Granted			
		Dolutegravir compound	Bilateral license on RPV				Not Filed			

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Nevirapine										
	100 mg	Nevirapine compound	Non assert declaration on NVP	AP9000188	5,11 Dihydro 6 H Dipyrido (3,2 B:2, 3 E)(1,4) Diazepin 6 Ones And Thions And Their Use For The Treatment Of Aids.	28/06/2010	Expired			
		Nevirapine compound	Non assert declaration on NVP	AP9000224	"5 11 Dihydro 6 H Dipyrido (3, 2 B:2', 3' E) (1,4) Diazepines And Their Use In The Prevention And Treatment Of Hiv Infection."	16/11/2010	Expired			
	200 mg	Nevirapine compound	Non assert declaration on NVP	AP9000188	5,11 Dihydro 6 H Dipyrido (3,2 B:2, 3 E)(1,4) Diazepin 6 Ones And Thions And Their Use For The Treatment Of Aids.	28/06/2010	Expired			
		Nevirapine compound	Non assert declaration on NVP	AP9000224	"5 11 Dihydro 6 H Dipyrido (3, 2 B:2', 3' E) (1,4) Diazepines And Their Use In The Prevention And Treatment Of Hiv Infection."	16/11/2010	Expired	60 tab/ caps	2.31	_
	400 mg	Nevirapine compound	Non assert declaration on NVP	AP9000188	5,11 Dihydro 6 H Dipyrido (3,2 B:2, 3 E)(1,4) Diazepin 6 Ones And Thions And Their Use For The Treatment Of Aids.	28/06/2010	Expired			
		Nevirapine compound	Non assert declaration on NVP	AP9000224	5 11 Dihydro 6 H Dipyrido (3, 2 B:2', 3' E) (1,4) Diazepines And Their Use In The Prevention And Treatment Of Hiv Infection.	16/11/2010	Expired			
	50 mg/ 5ml	Nevirapine compound	Non assert declaration on NVP	AP9000188	5,11 Dihydro 6 H Dipyrido (3,2 B:2, 3 E)(1,4) Diazepin 6 Ones And Thions And Their Use For The Treatment Of Aids.	28/06/2010	Expired			
		Nevirapine compound	Non asset declaration on NVP	AP9000224	5 11 Dihydro 6 H Dipyrido (3, 2 B:2', 3' E) (1,4) Diazepines And Their Use In The Prevention And Treatment Of Hiv Infection.	16/11/2010	Expired	240ml bottle	2.59	_

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Tenofovir/Lamivudine+Nevirapine	300/300+ 200 mg	Nevirapine compound		AP9000188	5,11 Dihydro 6 H Dipyrido (3,2 B:2, 3 E)(1,4) Diazepin 6 Ones And Thions And Their Use For The Treatment Of Aids.	28/06/2010	Expired			
		Nevirapine compound		AP9000224	5 11 Dihydro 6 H Dipyrido (3, 2 B:2', 3' E) (1,4) Diazepines And Their Use In The Prevention And Treatment Of HIV Infection.	16/11/2010	Expired			
		Tenofovir disoproxil compounds family					Not filed			
		Tenofovir disoproxil fumarate (TDF)					Not filed	_	_	
Zidovudine										
	10 mg/ ml							240ml	2.232	2.616
	100 mg	Zidovudine compound		AP8600044	Therapeutic Nucleosides.	15/09/2006	Expired			
								100 tab-cap	5.76	4.59
Efavirenz/Lamivudine/ Tenofovir	600/ 300/ 300	Tenofovir disoproxil compounds family	Bilateral on TAF & TDF & MPP license on TDF				Not filed			
		Tenofovir disoproxil fumarate (TDF)					Not filed	30 tab	9.78	_
Dolutegravir/Lamivudine/Tenofovir	300/ 300/ 50 mg	Tenofovir disoproxil compounds family	MPP license on adult formulation of DTG & DTG/ ABC combination and MPP license on peadiatric formulations of DTG				Not filed			
		Tenofovir disoproxil fumarate (TDF)					Not filed		_	_
		Dolutegravir compound					Not fied			

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Zidovudine/ Lamivudine										
	300/150 mg	Zidovudine compound	Bilateral license on TAF & TDF, Commitments not to enforce patents on emitricitrabine (FTC), TDF/ FTC/EFV & MPP license on TDF	AP8600044	"Therapeutic Nucleosides."	15/09/2006	Expired			
		Emtricitabine/lamivudine compounds family		AP9000163	Substituted: 1,3 Oxathiolanes With Antiviral Properties.	02/08/2010	Expired			
		Lamivudine/Emtricitabine compound family		AP9100255	1,3 Oxathiolane Nucleoside Analouges.	05/02/2011	Expired			
		Lamivudine crystal forms		AP9200395	Crystalline Oxathiolane Derivatives	06/02/2012	Expired			
		ABC/3TC, ABC/ FTC combinations with or without ZDV		AP9701089		28/03/2016	Granted			
		3TC+AZT tablets		AP9901519	Pharmaceutical Compositions Containing Lamivudine And Zidovudine.	29/10/2017	Granted	60 tab-cap	7.51	7.24
Tenofovir DF/ Lamivudine										
Efavirenz	100 mg	Efavirenz compound					Not filed			
	200 mg	Efavirenz compound					Not filed			
	300 mg	Efavirenz compound					Not filed			
	50 mg	Efavirenz compound					Not filed			
	600 mg	Efavirenz compound					Not filed			

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Tenofovir/ Emtricitabine/ Efavirenz	300/ 200/ 600 mg	Emtricitabine/ lamivudine compounds family		AP9000163	Substituted: 1,3 Oxathiolanes With Antiviral Properties.	02/08/2010	Expired			
		FTC/TDF or FTC/ TAF combinations		AP2000503348	Compositions And Methods For Combination Antiviral therapy	13/01/2024	Filed			
		TDF/FTC/EFV tablet formulations					Not filed			
		Tenofovir disoproxil compounds family					Not filed			
		Tenofovir disoproxil fumarate (TDF)					Not filed			
		Efavirenz compound					Not filed	30 tab-cap	10.66	9.24
Abacavir	20 mg/ ml	Abacavir compound	Bilateral licenses for sub-saharan Africa, Low income countries and least developed countries, & MMP license on peadiatric formulations of ABC	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		ABC/3TC, ABC/ FTC combinations with or without ZDV		AP9701089		28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted			
		Abacavir enzyme for intermediate process		AP9901721	Process For Preparing Enantiomerically Enriched N Derivatised Lactams.	20/08/2018	Granted			
		Abacavir manufacturing process		AP200001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted			
		Abacavir oral solution		AP200001878	Pharmacuetical Compositions Of (1 S,4 R) Cis 4 [2 Amino 6 Cyclopropylamino) 9 H Purin 9 Yl] 2 Cyclopentene 1 Methanol.	04/02/2019	Granted	240ml	8.86	6.05

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Abacavir	300 mg	Abacavir compound	Bilateral licenses for sub-saharan Africa, Low income countries and least developed countries.	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		ABC/3TC, ABC/ FTC combinations with or without ZDV		AP9701089		28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted			
		Abacavir enzyme for intermediate process		AP9901721	Process For Preparing Enantiomerically Enriched N Derivatised Lactams.	20/08/2018	Granted			
		Abacavir manufacturing process		AP200001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted	60 tab-cap	12.18	17.4
Abacavir/ Dolutegravir/ Lamivudine	600/ 50/ 300 mg	Abacavir compound	MPP license on adult formulation of DTG & DTG/ ABC combination	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Emtricitabine/lamivudine compounds family		AP9000163	Substituted: 1,3 Oxathiolanes With Antiviral Properties.	02/08/2010	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		Lamivudine crystal forms		AP9200395	Crystalline Oxathiolane Derivatives.	06/02/2012	Expired			
		ABC/3TC, ABC/ FTC combinations with or without ZDV		AP9701089	Synergistic Combinations Of Zidovudine, 1592 U89 And 3tc Or Ftc.	28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted			
		Abacavir enzyme for intermediate process		AP9901721	Process For Preparing Enantiomerically Enriched N Derivatised Lactams.	20/08/2018	Granted			
		Abacavir manufacturing process		AP200001790	Process For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted			
		Dolutegravir compound					Not filed			

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Abacavir	60 mg	Abacavir compound	Bilateral licenses for sub-saharan Africa, Low income countries and least developed countries, & MMP license on peadiatric formulations of ABC	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted	56 tab-cap	_	4.9
		Abacavir manufacturing process		AP200001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted			
Abacavir/Lamivudine	120/60 mg	Abacavir compound		AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089	Synergistic Combinations Of Zidovudine, 1592 U89 And 3tc Or Ftc.	28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate and its use in treating viral infections	14/05/2018	Granted	_	_	_
Abacavir/Lamivudine	60/30 mg	Abacavir compound	MPP license on pediatric formulations of ABC	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		Lamivudine crystal forms		AP9200395	Crystalline Oxathiolane Derivatives.	06/02/2012	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089	Synergistic Combinations Of Zidovudine, 1592 U89 And 3tc Or Ftc.	28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate and its use in treating viral infections	14/05/2018	Granted	60 tab-cap	3.96	_

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Abacavir/Lamivudine	600/300 mg	Abacavir compound	Bilateral licenses for sub-saharan Africa, Low income countries and least developed countries.	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Emtricitabine/lamivudine compounds family		AP9000163	Substituted: 1,3 Oxathiolanes with antiviral properties	02/08/2010	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		Lamivudine/Emtricitabine compound family		AP9100255	1,3 Oxathiolane Nucleoside Analouges.	05/02/2011	Expired			
		Lamivudine crystal forms		AP9200395	Crystalline Oxathiolane Derivatives.	06/02/2012	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089	Synergistic Combinations Of Zidovudine, 1592 U89 And 3tc Or Ftc.	28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted			
		Abacavir enzyme for intermediate process		AP9901721	Process For Preparing Enantiomerically Enriched N Derivatised Lactams.	20/08/2018	Granted			
		Abacavir manufacturing process		AP200001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted	30 tab-cap	14.2	14.52

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Abacavir/ Lamivudine/ Zidovudine	300/ 150/ 300 mg	Zidovudine compound		AP8600044	"Therapeutic Nucleosides."	15/09/2006	Expired			
		Abacavir compound		AP89000129	Therapeutic Nucleosides	26/06/2009	Expired			
		Emtricitabine/lamivudine compounds family		AP9000163	Substituted: 1,3 Oxathiolanes With Antiviral Properties.	02/08/2010	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		Lamivudine/Emtricitabine compound family		AP1000255	1,3 Oxathiolane Nucleoside Analouges.	05/02/2011	Expired			
		Lamivudine crystal forms		AP2000395	Crystalline Oxathiolane Derivatives	06/02/2012	Expired			
		ABC/3TC, ABC/ FTC combinations with or without ZDV		AP9701089	Synergistic Combinations Of Zidovudine, 1592 U89 And 3tc Or Ftc.	28/03/2016	Granted			
		3TC+AZT tablets		AP9901519	Pharmaceutical Compositions Containing Lamivudine And Zidovudine.	29/10/2017	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted			
		Abacavir enzyme for intermediate process		AP9901721	Process For Preparing Enantiomerically Enriched N Derivatised Lactams.	20/08/2018	Granted			
		Abacavir manufacturing process		AP200001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted	60 tab-cap	23.45	_
Darunavir	100 mg/ ml	Darunavir ethanolate solvate	Commitments not to enforce patents on DRV in Sub-Saharan Africa and LDCs & Commitment not to enforce patents on peadiatric DRV	AP200403191	Pseudopolymorphic Forms Of Hiv Protease Inhibitor	16/05/2023	Granted			
		Darunavir compound					Not filed			
Darunavir	150 mg	Darunavir ethanolate solvate	Commitments not to enforce patents on DRV in Sub-Saharan Africa and LDCs & Commitment not to enforce patents on peadiatric DRV	AP200403191	Pseudopolymorphic Forms Of Hiv Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not filed			
		Darunavir compound					Not filed			

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Darunavir	300 mg	Darunavir ethanolate solvate	Commitments not to enforce patents on DRV in Sub-Saharan Africa and LDCs	AP200403191	Pseudopolymorphic Forms Of HIV Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not filed			
		Darunavir compound					Not filed	60 tab-cap	79.23	
Darunavir	400 mg	Darunavir ethanolate solvate	Commitments not to enforce patents on DRV in Sub-Saharan Africa and LDCs	AP200403191	Pseudopolymorphic Forms of HIV Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not filed			
		Darunavir compound					Not filed	60 tab-cap	36.54	
Darunavir	600 mg	Darunavir ethanolate solvate	Commitments not to enforce patents on DRV in Sub-Saharan Africa and LDCs	AP200403191	Pseudopolymorphic Forms Of HIV Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not filed			
		Darunavir compound					Not filed	60 tab-cap	54.81	
Darunavir	75 mg	Darunavir ethanolate solvate	Commitments not to enforce patents on DRV in Sub-Saharan Africa and LDCs & Commitment not to enforce patents on peadiatric DRV	AP200403191	Pseudopolymorphic Forms of HIV Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not filed			
		Darunavir compound					Not filed	_	_	
Darunavir	800 mg	Darunavir ethanolate solvate	Commitments not to enforce patents on DRV in Sub-Saharan Africa and LDCs	AP200403191	Pseudopolymorphic Forms of HIV Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not filed			
		Darunavir compound					Not filed	_	_	
Saquinavir										

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Atazanavir/ Ritonavir	300/ 100 mg	Atazanavir compound family	MPP license on ATV & MPP license on (LPR/r) and RPV for Africa				Not filed			
		Ritonavir compound					Not filed			
		Atazanavir bisulfate salt					Not filed	30 tab-cap	19.27	27.12
Lopinavir/ Ritonavir	100mg/ 25mg	Lopinavir compound	MPP license on ATV & MPP license on (LPR/r) and RPV for Africa				Not filed	60 tab-cap	6.24	
	200mg/ 50mg	Lopinavir compound					Not filed	120 tab-cap	19.68	
	80/ 20mg/ ml	Ritonavir compound					Not filed	60 ml	9.11	
Raltegravir	400 mg	Ritonavir compound	MPP license on ATV & MPP license on (LPR/r) and RPV for Africa				Not filed	60 tab-cap	52.13	
	25mg	Ritonavir compound	MPP license on ATV & MPP license on (LPR/r) and RPV for Africa & MPP license on pediatric formulations of (LPR/r and RPV for Africa				Not filed	56 tab-cap	18.42	
Etravirine	200 mg , 100mg & 25 mg	Etravirine compound		AP200102121	HIV Replication Inhibiting Pyrimidines.	24/09/2019	Granted	_	_	
		Etravirine solid formulations		AP200102155	2.4 Disubstituted Triazine Derivatives	11/04/2019	Granted	112 tab-cap	37.98	
		Etravirine solid formulations		AP200202482	Pharmaceutical Compositions Of Antiviral Compoundsand Processes For Preparation	31/08/2020	Granted	_	_	
Medicines for opportunistic infections										
Fluconazole	200mg							100 tab-cap	7.03	
	50mg/ 5ml							35 ml	2.37	
	2mg/ ml							100 ml	2.32	4.02
Cotrimoxazole										
First Line TB Medicines										

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Isoniazid										
2-FDC RH										
3-FDC RHZ (Rifampicin, Isoniazid, Pyrazinamide) dispersible	60/30/ 150 mg							84 tab-cap	1.96	
4-FDC RHZE	150/75/ 400/ 275							672 tab-cap	40.71	
Streptomycin										
MDR TB Medicines										
Capreomycin	I g							1 vial	4.7	
Kanamycin	1g							1 vial	1.17	
Cycloserine	250 mg							100 tab-cap	33	
Ethionamide	250 mg							90 tab-cap	5.54	
Levofloxacin										
Amikacin										
Moxifloxacin	400mg							100 tab-cap	44.6	
TB-XDR medicine										
Bedaquiline	100 mg	Bedaquiline compounds family		AP200503210	Quinoline Derivatives And Their Use As Mycobacterial Inhibitors.	18/07/2023	Granted			
		Bedaquiline to treat MDR TB		AP2005603828	Use Of Substituted Quinoline Derivatives For The Treatment Of Drug Resistant Mycobacterial Diseases	24/05/2025	Granted			
		Bedaquiline to treat latent TB		AP200704054	Quinoline Derivatives For The Treatment Of Latent Tuberculosis.	12/08/2025	Granted			
		Bedaquiline fumarate salt		AP200904870	Fumarate Salt Of (Alpha S, Beta R) 6 Bromo Alpha [2 (Dimethylamino) Ethyl] 2 Methoxy Alpha 1 Naphthalenyl Beta Phenyl 3 Quinolineethanol	12/03/2027	Granted	100 tab-cap	3000	

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Clofazimine	100 mg							100 tab-cap	126.72	
Linezolid	600 mg							20 tab-cap	109.6	
Cytotoxics/ anticancers										
Anastrozole	I mg							30 tab-cap	_	15.81
Bleomycin	15 IU							I vial	12.15	
Docetaxel										
Rituximab	10 mg/ml							1 vial	_	136.72
Hepatitis C treatment										
Ribavarin	200mg							42 tab-cap	12.28	
Daclatasvir	60 mg	Daclatasvir crystal-line forms	MPP license on DCV				Not Filed			
		Daclatasvir com-pound family					Not Filed	84 tab-cap	63,000	
Sofosbuvir+ Daclatasvir	400+ 60 mg	Sofosbuvir process-es & intermediates	Bilateral license on SOF, SOF/ledipasvir, SOF/ VEL/voxilaprevir & MPP licenselicense on DCV	AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir process-es & intermediates		AP201206535	Sofosbuvir processes & intermediates	31/03/2031	Filed			
		Sofosbuvir compo-sitions		AP201407575	Not Available	14/09/2032	Filed			
		Sofosbuvir compo-sitions		AP201407699	Not Available	27/11/2032	Filed			
		Daclatasvir crystal-line forms					Not Filed			
		Daclatasvir com-pound family					Not Filed		147,000	
velpatasvir										

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Sofosbuvir/ Velpatasvir	400/ 100 mg	Sofosbuvir processes & intermediates	Bilateral license on SOF, SOF/ledipasvir, SOF/VEL/ voxilaprevir	AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir processes & intermediates		AP201206535	Not Availabe	31/03/2031	Filed			
		Sofosbuvir compositions		AP201407575	Not Available	14/09/2032	Filed			
		Velpatasvir compounds family		AP201306877	Not Available	16/11/2032	Filed			
		Sofosbuvir compositions		AP201407699	Not Available	27/11/2032	Granted		74,760	
Sofosbuvir/ Velpatasvir/ Voxilaprevir	400/ 100/ 100 mg	Sofosbuvir processes & intermediates	Bilateral license on SOF, SOF/ledipasvir, SOF/ VEL/voxilaprevir & MPP licenselicense on DCV	AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir processes & intermediates		AP201206535	Not Available	31/03/2031	Filed			
		Sofosbuvir compositions		AP201407575	Not Available	14/09/2032	Filed			
		Velpatasvir compounds family		AP201306877	Not Available	16/11/2032	Granted			
		Sofosbuvir compositions		AP201407699	Not Available	27/11/2032	Filed			
		Voxilaprevir & combinations		AP201408166	Inhibitors Of Hepatitis C Virus	07/02/2033	Granted			
Sofosbuvir	400 mg	Sofosbuvir processes & intermediates	Bilateral license on SOF, SOF/ledipasvir, SOF/ VEL/voxilaprevir & MPP licenselicense on DCV	AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir processes & intermediates		AP201206535	Not Available	31/03/2031	Filed			
		Sofosbuvir compositions		AP201407575	Not Available	14/09/2032	Filed			
		Sofosbuvir compositions		AP201407699	Not Available	27/11/2032	Granted	84 tab-cap	84,000	

Generic name/ ARV formulations	Strength	Patent description	License description	Patent application No	Invention Title	Uganda expiry date	Patent status in Uganda	Package	Supplier price (USD)	Buyer price (USD)
Sofosbuvir/ ledipasvir	400/ 90 mg	LDV compounds family	Bilateral license on SOF, SOF/ledipasvir, SOF/VEL/ voxilaprevir	AP201608993	Not Available	05/12/2030	Filed			
		LDV compounds family		AP201105987	Antiviral Compounds	05/12/2030	Granted			
		Sofosbuvir process-es & intermediates		AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir process-es & intermediates		AP201206535	Not Available	31/03/2031	Filed			
		Sofosbuvir compo-sitions		AP201407575	Not Available	14/09/2032	Filed			
		Sofosbuvir compo-sitions		AP201407699	Not Available	27/11/2032	Filed			
		SOF/LDV compo-sitions		AP201508630	Not Available	30/01/2034	Filed	84 tab-cap	94,500	

Source: MedsPal, http://www.medspal.org; http://mshpriceguide.org/en/drug-search-page-2/.

Annex II: Medicine and patent and price information for Kenya

Generic name/ ARV formulations	Strengths	Patent description	License	Kenya patent No./ Patent app. No.	Invention Title	Kenya expiry date	Patent status in Ke	Package	Supplier price (USD)	Buyer price (USD)
Dolutegravir	10 mg & 25 mg	Dolutegravir compound	MPP license on pediatric formulations of DTG				Not Filed			
Dolutegravir	50 mg	Dolutegravir compound	MPP license on adult formulation of DTG & DTG/ ABC combination and MPP license on pediatric formulations of DTG				Not Filed			
Dolutegravir/ Rilpivirine	50/25 mg	Rilpivirine compound & combinations	Bilateral license on RPV	AP200402993	HIV Replication Inhibiting Pyrimidines	08/09/2022	Granted			
		Rilpivirine compound & combinations		AP200603551	Combinations Of A Pyrimidine Containing Nnrti With Rt Inhibitors	09/03/2024	Granted			
		Rilpivirine compound & combinations		AP200703934	Hydrochloride Of 4 [[4 [[4 (2 Cyanoethenyl) 2,6 Dimethylphenyl] Amino] 2 Pyrimidinyl]Amino] Benzonitrile.	09/02/2025	Granted			
		Rilpivirine compound & combinations		AP200703933	Fumarate Of 4 [[4 [[4 (2 Cyanoethenyl) 2,6 Dimethylphenyl] Amino] 2 Pyrimidinyl]Amino] Benzonitrile	09/02/2025	Granted			
		Dolutegravir compound					Not filed			

Abacavir/ Dolutegravir/ Lamivudine	600/ 50/ 300 mg	Abacavir compound	MPP license on adult formulation of DTG & DTG/ABC combination	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Emtricitabine/lamivudine compounds family		AP9000163	Substituted: 1,3 Oxathiolanes With Antiviral Properties.	02/08/2010	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		Lamivudine crystal forms		AP200395	Crystalline Oxathiolane Derivatives.	06/02/2012	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089	Synergistic Combinations Of Zidovudine, 1592 U89 And 3tc Or Ftc.	28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted			
		Abacavir enzyme for intermediate process		AP9901721	Process For Preparing Enantiomerically Enriched N Derivatised Lactams.	20/08/2018	Granted			
		Abacavir manufacturing process		AP200001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted			
		Dolutegravir in combination with ABC and 3TC		AP201206445	Antiviral Therapy	24/01/2031	Granted			
		Dolutegravir compound					Not Filed			
Tenofovir/ Lamivudine/ Dolutegravir	300/ 300/ 50 mg	Tenofovir disoproxil compounds family	MPP license on adult formulation of DTG & DTG/ABC combination and MPP license on pediatric formulations of DTG				Not Filed			
		Tenofovir disoproxil fumarate (TDF)					Not Filed			
		Dolutegravir compound					Not Filed			

Nevirapine	100 mg & 400 mg	Nevirapine compound		AP9000188	5,11 Dihydro 6 H Dipyrido (3,2 B:2, 3 E)(1,4) Diazepin 6 Ones And Thions and their use for the treatment of AIDS.	28/06/2010	Expired			
		Nevirapine compound		AP9000224	"5 11 Dihydro 6 H Dipyrido (3, 2 B:2', 3' E) (1,4) Diazepines and their use in the prevention and treatment of HIV infection."	16/11/2010	Expired			
	200 mg	Nevirapine compound		AP9000188	5,11 Dihydro 6 H Dipyrido (3,2 B:2, 3 E)(1,4) Diazepin 6 Ones And Thions and their use for the treatment of AIDS.	28/06/2010	Expired			
		Nevirapine compound		AP9000224	"5 11 Dihydro 6 H Dipyrido (3, 2 B:2', 3' E) (1,4) Diazepines and their use in the prevention and treatment of HIV infection."	16/11/2010	Expired	60 tab/caps	2.31	_
	50 mg/ 5ml	Nevirapine compound		AP9000188	5,11 Dihydro 6 H Dipyrido (3,2 B:2, 3 E)(1,4) Diazepin 6 Ones and Thions and their use for the treatment of AIDS.	28/06/2010	Expired			
		Nevirapine compound		AP9000224	"5 11 Dihydro 6 H Dipyrido (3, 2 B:2', 3' E) (1,4) Diazepines and their use in the prevention and treatment of HIV infection."	16/11/2010	Expired	240ml bottle	2.59	_
Tenofovir/ Lamivudine+ Nevirapine	300/ 300+ 200 mg	Nevirapine compound		AP9000188		28/06/2010	Expired			
		Nevirapine compound		AP9000224		16/11/2010	Expired			
		Tenofovir disoproxil compounds family					Not Filed			
		Tenofovir disoproxil fumarate (TDF)					Not Filed	_	_	_
Zidovudine	10 mg/ ml							240ml	2.232	2.616
	100 mg	Zidovudine compound		AP8600044	"Therapeutic Nucleosides."	15/09/2006	Expired			
								100 tab-cap	5.76	4.59

Abacavir/ Lamivudine/ Zidovudine	300/ 150/ 300 mg	Zidovudine compound		AP8600044	"Therapeutic Nucleosides."	15/09/2006	Expired			
		Abacavir compound		AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Emtricitabine/lamivudine compounds family		AP9000163	Substituted: 1,3 Oxathiolanes With Antiviral Properties.	02/08/2010	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		Lamivudine/Emtricitabine compound family		AP9100255	1,3 Oxathiolane Nucleoside Analouges.	05/02/2011	Expired			
		Lamivudine crystal forms		AP9200395	Crystalline Oxathiolane Derivatives.	06/02/2012	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089	Synergistic Combinations Of Zidovudine, 1592 U89 And 3tc Or Ftc.	28/03/2016	Granted			
		3TC+AZT tablets		AP9901519	Pharmaceutical Compositions Containing Lamivudine and Zidovudine.	29/10/2017	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate and its use in treating viral infections	14/05/2018	Granted			
		Abacavir enzyme for intermediate process		AP9901721	Process For Preparing Enantiomerically Enriched N Derivatised Lactams.	20/08/2018	Granted			
		Abacavir manufacturing process		AP20001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted	60 tab-cap	23.45	_
Dolutegravir/ Lamivudine/Tenofovir	300/ 300/ 50 mg	Tenofovir disoproxil compounds family	MPP license on adult formulation of DTG & DTG/ ABC combination and MPP license on peadiatric formulations of DTG				Not Filed			
		Tenofovir disoproxil fumarate (TDF)					Not Filed			
		Dolutegravir compound					Not Filed			

Zidovudine/ Lamivudine	300/ 150 mg	Zidovudine compound		AP8600044	“Therapeutic Nucleosides.”	15/09/2006	Expired			
		Emtricitabine/lamivudine compounds family		AP9000163	Substituted: 1,3 Oxathiolanes With Antiviral Properties.	02/08/2010	Expired			
		Lamivudine/Emtricitabine compound family		AP9100255	1,3 Oxathiolane Nucleoside Analouges.	05/02/2011	Expired			
		Lamivudine crystal forms		AP9200395	Crystalline Oxathiolane Derivatives.	06/02/2012	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089		28/03/2016	Granted			
		3TC+AZT tablets		AP9901519	Pharmaceutical Compositions Containing Lamivudine And Zidovudine.	29/10/2017	Granted	60 tab-cap	7.51	7.24
Tenofovir DF/ Lamivudine										
Efavirenz	100 mg, 200 mg, 300 mg, 50 mg & 600 mg	Efavirenz compound					Not Filed			
Tenofovir/ Emtricitabine/ Efavirenz	300/ 200/ 600 mg	Emtricitabine/lamivudine compounds family	Bilateral license on TAF and TDF, MPP license on TDF & Commitment not to enforce patents on FTC, TDF/FTC and TDF/ FTC/EFV	AP9000163	Substituted: 1,3 Oxathiolanes With Antiviral Properties.	02/08/2010	Expired			
		FTC/TDF or FTC/ TAF combinations		AP2000503348	Compositions And Methods For Combination Antiviral-therapy	13/01/2024	Filed			
		TDF/FTC/EFV tablet formulations					Not Filed			
		Tenofovir disoproxil compounds family					Not Filed			
		Tenofovir disoproxil fumarate (TDF)					Not Filed			
		Efavirenz compound					Not Filed	30 tab-cap	10.66	9.24
Tenofovir/ Lamivudine/ Efavirenz	300/ 300/600 mg	Tenofovir disoproxil compounds family	Bilateral license on TAF and TDF, MPP license on TDF				Not Filed			
		Tenofovir disoproxil fumarate (TDF)					Not Filed	30 tab	9.78	_

Abacavir	20 mg/ml	Abacavir compound	Bilateral licenses for sub-saharan Africa, Low income countries and least developed countries, & MMP license on peadiatric formulations of ABC	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089		28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted			
		Abacavir enzyme for intermediate process		AP9901721	Process For Preparing Enantiomerically Enriched N Derivatised Lactams.	20/08/2018	Granted			
		Abacavir manufacturing process		AP200001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted			
		Abacavir oral solution		AP200001878	Pharmacuetical Compositions Of (1 S,4 R) Cis 4 [2 Amino 6 Cyclopropyl-amino) 9 H Purin 9 Yl] 2 Cyclopentene 1 Methanol.	02/04/2019	Granted	240ml	8.86	6.05
Abacavir	300 mg	Abacavir compound	Bilateral licenses for sub-saharan Africa, Low income countries and least developed countries	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089		28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted			
		Abacavir enzyme for intermediate process		AP9901721	Process For Preparing Enantiomerically Enriched N Derivatised Lactams.	20/08/2018	Granted			
		Abacavir manufacturing process		AP200001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted	60 tab-cap	12.18	17.4

Abacavir	60 mg	Abacavir compound	Bilateral licenses for sub-saharan Africa, Low income countries and least developed countries, & MMP license on peadiatric formulations of ABC	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted	56 tab-cap	_	4.9
		Abacavir manufacturing process		AP200001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Graned			
Abacavir/ Lamivudine	120/60 mg	Abacavir compound	MMP license on peadiatric formulations of ABC	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089	Synergistic Combinations Of Zidovudine, 1592 U89 And 3tc Or Ftc.	28/03/2016	Granted	_	_	_
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted			
Abacavir/ Lamivudine	60/30 mg	Abacavir compound	MMP license on peadiatric formulations of ABC	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		Lamivudine crystal forms		AP9200395	Crystalline Oxathiolane Derivatives.	06/02/2012	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089	Synergistic Combinations Of Zidovudine, 1592 U89 And 3tc Or Ftc	28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted	60 tab-cap	3.96	_

Abacavir/ Lamivudine	600/ 300 mg	Abacavir compound	Bilateral licenses for sub-saharan Africa, Low income countries and least developed countries	AP8900129	Therapeutic Nucleosides	26/06/2009	Expired			
		Emtricitabine/lamivudine compounds family		AP9000163	Substituted: 1,3 Oxathiolanes With Antiviral Properties.	02/08/2010	Expired			
		Abacavir compound		AP9000234	Therapeutic Nucleosides	21/12/2010	Expired			
		Lamivudine/Emtricitabine compound family		AP9100255	1,3 Oxathiolane Nucleoside Analouges.	05/02/2011	Expired			
		Lamivudine crystal forms		AP9200395	Crystalline Oxathiolane Derivatives.	06/02/2012	Expired			
		ABC/3TC, ABC/FTC combinations with or without ZDV		AP9701089	Synergistic Combinations Of Zidovudine, 1592 U89 And 3tc Or Ftc.	28/03/2016	Granted			
		Abacavir hemisulfate salt & combinations		AP9901688	Carbocylic Nucleoside Hemisulfate And Its Use In Treating Viral Infections	14/05/2018	Granted			
		Abacavir enzyme for intermediate process		AP9901721	Process For Preparing Enantiomerically Enriched N Derivatised Lactams.	20/08/2018	Granted			
		Abacavir manufacturing process		AP200001790	Proces For The Synthesis Of Chloropurine Intermediates.	14/10/2018	Granted	30 tab-cap	14.2	14.52
Darunavir	100 mg/ml	Darunavir ethanolate solvate	Commitment not to enforce patents on DRV on Sub-Saharan Africa and LDCs & Commitment not to enforce patents on peadiatric DRV	AP200403191	Pseudopolymorphic Forms Of Hiv Protease Inhibitor	16/05/2023	Granted			
		Darunavir compound					Not Filed			
Darunavir	150 mg	Darunavir ethanolate solvate	Commitment not to enforce patents on DRV on Sub-Saharan Africa and LDCs & Commitment not to enforce patents on peadiatric DRV	AP200403191	Pseudopolymorphic Forms Of Hiv Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not Filed			
		Darunavir compound					Not Filed			

Darunavir	300 mg	Darunavir ethanolate solvate	Commitment not to enforce patents on DRV on Sub-Saharan Africa and LDCs	AP200403191	Pseudopolymorphic Forms Of Hiv Protease Inhibitor	16/05/2023	Grated			
		Darunavir/ritonavir combinations					Not Filed			
		Darunavir compound					Not Filed	60 tab-cap	79.23	
Darunavir	400 mg	Darunavir ethanolate solvate	Commitment not to enforce patents on DRV on Sub-Saharan Africa and LDCs	AP200403191	Pseudopolymorphic Forms Of Hiv Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not Filed			
		Darunavir compound					Not Filed	60 tab-cap	36.54	
Darunavir	600 mg	Darunavir ethanolate solvate		AP200403191	Pseudopolymorphic Forms Of Hiv Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not Filed			
		Darunavir compound					Not Filed	60 tab-cap	54.81	
Darunavir	75 mg	Darunavir ethanolate solvate	Commitment not to enforce patents on DRV on Sub-Saharan Africa and LDCs & Commit-ment not to enforce patents on peadiatric DRV	AP200403191	Pseudopolymorphic Forms Of Hiv Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not Filed			
		Darunavir compound					Not Filed	_	_	
Darunavir	800 mg	Darunavir ethanolate solvate	Commitment not to enforce patents on DRV on Sub-Saharan Africa and LDCs	AP200403191	Pseudopolymorphic Forms Of Hiv Protease Inhibitor	16/05/2023	Granted			
		Darunavir/ritonavir combinations					Not Filed			
		Darunavir compound					Not Filed	_	_	

Darunavir/ Cobicistat	800/150 mg	Darunavir ethanolate solvate	Bilateral license on COBI, Commitment not to enforce patents on DRV on Sub-Saharan Africa and LDCs & MPP license on COBI	AP200403191	Pseudopolymorphic Forms of HIV Protease Inhibitor	16/05/2023	Granted			
		Cobicistat compound		AP200804720	Modulators of Pharmacokinetic Properties of Therapeutics	07/06/2027	Granted			
		Cobicistat compound		AP201307042	Modulators of Pharmacokinetic Properties of Therapeutics	22/02/2028	Granted			
		Cobicistat compound		AP200904964	Modulators of Pharmacokinetic Properties Of Therapeutics	22/02/2028	Granted			
		Cobicistat tablets		AP2010055429	The Use Of Solid Carrier Particles To Improve The Processability Of A Pharmaceutical Agent	05/01/2029	Granted			
		Cobicistat intermediates		AP201105864	Method Of Preparing An Inhibitor Of Cytochrome P540 Monooxygenase, And Intermediates Involved	01/04/2030	Granted			
		Cobicistat tablets		AP201105857	Tablets For Combination Therapy	02/04/2030	Granted			
		Darunavir compound					Not Filed			
Darunavir/ Emtricitabine/ Cobicistat/ Tenofovir alafenamide	800/ 200/ 150/ 10 mg	Tenofovir alafenamide fumarate (TAF)		AP200302724	Prodrugs Of Phosphonate Nucleotide Analogues And Methods For Selecting And Making Same.	20/07/2021	Granted			
		Cobicistat compound		AP200804720	Modulators Of Pharmacokinetic Properties Of Therapeutics	07/06/2027	Granted			
		Cobicistat compound		AP201307042	Modulators Of Pharmacokinetic Properties Of Therapeutics	22/02/2028	Granted			
		Cobicistat compound		AP20904964	Modulators Of Pharmacokinetic Properties Of Therapeutics	22/02/2028	Granted			
		Cobicistat tablets		AP2010055429	The Use Of Solid Carrier Particles To Improve The Processability Of A Pharmaceutical Agent	05/01/2029	Granted			
		Cobicistat tablets		AP201105857	Tablets For Combination Therapy	02/04/2030	Granted			
Saquinavir										

Atazanavir/ Ritonavir	300/ 100 mg	LPV/r heat-stable formulations	MPP license on ATV & MPP license on LPV/r and RTV for Africa				Not Filed			
		Atazanavir compound family					Not Filed			
		Ritonavir compound					Not Filed			
		Atazanavir bisulfate salt					Not Filed			
		Ritonavir and LPV/r heat-stable formulations					Not Filed	30 tab-cap	19.27	27.12
Lopinavir/ Ritonavir	100/ 25 mg	LPV/r heat-stable formulations					Not Filed			
		Lopinavir compound					Not Filed			
		Ritonavir compound					Not Filed			
		Ritonavir and LPV/r heat-stable formulations					Not Filed			
	200/ 50mg	LPV/r heat-stable formulations					Not filed			
		Lopinavir compound					Not filed			
		Ritonavir compound					Not filed			
		Ritonavir and LPV/r heat-stable formulations					Not Filed			
	80/ 20 mg/ ml	Lopinavir compound					Not Filed			
		Ritonavir compound					Not Filed			

Raltegravir	100 mg, & 600 mg	Raltegravir potassium salt	MPP license on pea-diatric formulations of RAL				Not Filed			
		Raltegravir com-pound					Not Filed			
	25 mg	Raltegravir potassium salt	MPP license on pea-diatric formulations of RAL				Not Filed			
		Raltegravir com-pound					Not Filed	60 tab-cap	52.13	
	400 mg	Raltegravir potassium salt	MPP license on pea-diatric formulations of RAL				Not Filed	56 tab-cap	18.42	
		Raltegravir com-pound					Not Filed			
Etravine	100mg, 200 mg & 25 mg	Etravirine compound		AP200102121	Hiv Replication Inhibiting Pyrimidines.	24/09/2019	Granted	_	_	_
		Etravirine solid formulations		AP200202482	Pharmaceutical Com-positions Of Antiviral Compoundsand Processes For Preparation	31/08/2020	Granted	_	_	_
		Etravirine solid formulations		AP200102155	2.4 Disubstituted Triazine Derivatives	11/04/2019	Granted	112 tab-cap	37.98	_
Medicines for opportunistic infec-tions										
Fluconazole	200mg							100 tab-cap	7.03	_
	50mg/ 5ml							35 ml	2.37	_
	2mg/ ml							100 ml	2.32	4.02
Cotrimoxazole										
First Line TB Med-icines										
Isoniazid										
2-FDC RH										
3-FDC RHZ	60/ 30/ 150 mg							84 tab-cap	1.96	
4-FDC RHZE	150/ 75/ 400/ 275							672 tab-cap	40.71	
Streptomycin										
MDR TB Medicines										

Capreomycin	I g							1 vial	4.7	
Kanamycin	1g							1 vial	1.17	
Cycloserine	250 mg							100 tab-cap	33	
Ethionamide	250 mg							90 tab-cap	5.54	
Levofloxacin										
Amikacin										
Moxifloxacin	400mg							100 tab-cap	44.6	
TB-XDR medicine										
Bedaquiline	100 mg	Bedaquiline compounds family		AP200503210	Quinoline Derivatives And Their Use As Mycobacterial Inhibitors.	18/07/2023	Granted			
		Bedaquiline to treat MDR TB		AP200603828	Use Of Substituted Quinoline Derivatives For The Treatment Of Drug Resistant Mycobacterial Diseases	24/05/2025	Granted			
		Bedaquiline to treat latent TB		AP200704054	Quinoline Derivatives For The Treatment Of Latent Tuberculosis.	12/08/2025	Granted			
		Bedaquiline fumarate salt		AP200904870	Fumarate Salt Of (Alpha S, Beta R) 6 Bromo Alpha [2 (Dimethylamino) Ethyl] 2 Methoxy Alpha 1 Naphthalenyl Beta Phenyl 3 Quinolineethanol	12/03/2027	Granted	100 tab-cap	3000	
Clofazimine	100 mg							100 tab-cap	126.72	
Linezolid	600 mg							20 tab-cap	109.6	
Cytotoxics/ anticancers										
Anastrozole	1 mg							30 tab-cap	_	15.81
Bleomycin	15 IU							I vial	12.15	
Docetaxel										
Rituximab	10 mg/ml							1 vial	_	136.72
Hepatitis C treatment										
Ribavarin	200mg							42 tab-cap	12.28	

Daclatasvir	30 mg	Daclatasvir crystalline forms	MPP license on DCV				Not filed			
		Daclatasvir compound family					Not Filed			
Daclatasvir	60 mg	Daclatasvir crystalline forms	MPP license on DCV				Not filed			
		Daclatasvir compound family					Not filed	84 tab-cap	63,000	
Sofosbuvir+ Daclatasvir	400+60 mg	Sofosbuvir processes & intermediates	Bilateral license on SOF, SOF/ledipasvir, SOF/VEL/voxilaprevir & MPP license on DCV	AP201206535	Not Available	31/03/2031	Filed			
		Sofosbuvir processes & intermediates		AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir compositions		AP201407575	Not Available	14/09/2032	Filed			
		Sofosbuvir compositions		AP201407699	Not Available	27/11/2032	Granted			
		Sofosbuvir compounds family					Not filed			
		Daclatasvir crystalline forms					Not filed			
		Daclatasvir compound family					Not filed			
		Sofosbuvir prodrug					Not filed		147,000	
Velpatasvir										
Sofosbuvir/Velpatasvir	400/100 mg	Sofosbuvir processes & intermediates	Bilateral license on SOF, SOF/ledipasvir, SOF/VEL/voxilaprevir	AP201206535	Not Available	31/03/2031	Filed			
		Sofosbuvir processes & intermediates		AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir compositions		AP201407575	Not Available	14/09/2032	Filed			
		Velpatasvir compounds family		AP201306877	Not Available	16/11/2032	Granted			
		Sofosbuvir compositions		AP201407699	Not Available	27/11/2032	Granted			
		Sofosbuvir compounds family					Not Filed			
		Sofosbuvir prodrug					Not Filed		74,760	

Sofosbuvir/Velpatasvir/Voxilaprevir	400/ 100/ 100 mg	Sofosbuvir processes & intermediates	Bilateral license on SOF, SOF/ledipasvir, SOF/VEL/voxilaprevir	AP201206535	Not Available	31/03/2031	Filed			
		Sofosbuvir processes & intermediates		AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir compositions		AP201407575	Not Available	14/09/2032	Filed			
		Velpatasvir compounds family		AP201306877	Not Available	16/11/2032	Granted			
		Sofosbuvir compositions		AP201407699	Not Available	27/11/2032	Filed			
		Voxilaprevir & combinations		AP2011408166	Inhibitors Of Hepatitis C Virus	07/02/2033	Granted			
		Sofosbuvir compounds family					Not Filed			
		Sofosbuvir prodrug					Not filed			
Sofosbuvir	400 mg	Sofosbuvir processes & intermediates	Bilateral license on SOF, SOF/ledipasvir, SOF/VEL/voxilaprevir	AP201206535	Not Available	31/03/2031	Filed			
		Sofosbuvir processes & intermediates		AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir compositions		AP201407575	Not Available	14/09/2032	Filed			
		Sofosbuvir compositions		AP201407699	Not Available	27/11/2032	Granted			
		Sofosbuvir compounds family					Not Filed			
		Sofosbuvir prodrug					Not filed	84 tab-cap	84,000	

Sofosbuvir+ Daclatasvir	400+ 60 mg	Sofosbuvir processes & intermediates	Bilateral license on SOF, SOF/ledipasvir, SOF/VEL/voxilaprevir & MPP license on DCV	AP201206535	Not Available	31/03/2031	Filed			
		Sofosbuvir processes & intermediates		AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir compositions		AP201407575	Not Available	14/09/2032	Filed			
		Sofosbuvir compositions		AP201407699	Not Available	27/11/2032	Filed			
		Sofosbuvir compounds family					Not Filed			
		Daclatasvir crystalline forms					Not Filed			
		Daclatasvir compound family					Not Filed			
		Sofosbuvir prodrug					Not Filed			
Sofosbuvir/ Ledipasvir	400/ 90 mg	LDV compounds family	Bilateral license on SOF, SOF/ledipasvir, SOF/VEL/voxilaprevir	AP201608993	Not Available	05/12/2030	Filed			
		LDV compounds family		AP201105987	Antiviral Compounds	05/12/2030	Granted			
		Sofosbuvir processes & intermediates		AP201206535	Not Available	31/03/2031	Filed			
		Sofosbuvir processes & intermediates		AP201206543	Nucleoside Phosphoramidates	31/03/2031	Granted			
		Sofosbuvir compositions		AP201407575	Not Available	14/09/2032	Filed			
		Sofosbuvir compositions		AP201407699	Not Available	27/11/2032	Filed			
		SOF/LDV compositions		AP201508630	Not Available	30/01/2034	Filed			
		Sofosbuvir compounds family					Not Filed			
		Sofosbuvir prodrug					Not Filed	84 tab-cap	94,500	

Source: MedsPal, http://www.medspal.org; http://mshpriceguide.org/en/drug-search-page-2/.

(Footnotes)

1 Section 8 (f)
2 This period was extended by the WTO council until 2033 for pharmaceuticals
3 Regulation 3
4 Section 10
5 Section 10(2)
6 Section 11
7 Section 12
8 The current waiver ends on 1 January 2033

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