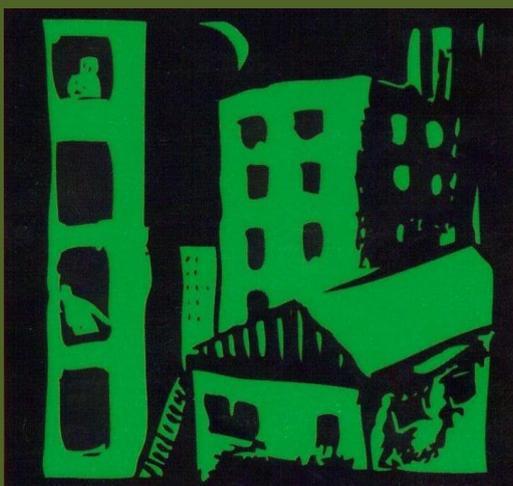


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**States' obligations
in relation to access
to medicines:
Revisiting Kenyan
High Court decision
in *P.A.O and Others
v Attorney-General
and Another***

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1 INTRODUCTION

Recently a Kenyan High court in *P.A.O and others v Attorney General and another*¹ (hereinafter *P.A.O*) handed down a judgment in relation to sections 2, 32, and 34 of the Anti-Counterfeit Act² vis-à-vis Kenya's obligations under international human rights law and the Constitution. For many Africans, access to medicines has remained a great challenge not least because of high prices mainly due to patent on these medicines. Although recent

¹ *PA.O and others v Attorney General and another* High Court of Kenya at Nairobi Petition No. 409 of 2009, (Judgment 2012).

² Anti-Counterfeit Act 13 of 2008.

developments across Africa had shown that modest progress has been made in realizing access to medicines for people living with HIV, a great percentage of those in need of these medicines are not receiving them. One of the major obstacles to access to medicines in Africa is patent rights enjoyed by pharmaceutical companies on essential medicines such as anti-retroviral drugs.

It must be recalled that during the Doha Declaration on intellectual property and public health,³ members of the World Trade Organization (WTO) agreed that countries could invoke the flexibilities contained in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement to facilitate access to life-saving medications for their people. Sadly however, the victory at Doha by activists is being undermined by the activities of pharmaceutical companies and some developed countries, who have not only continued to oppose the use of TRIPS flexibilities, but have also pressurised developing countries to adopt TRIPS-plus intellectual property regime. This situation is not only at variance with the spirit of Doha but also raises the question of states' duties to protect and promote the rights to health and life of their people.

Against this backdrop this paper examines the decision of the Kenyan High Court in *PA.O and others v Attorney General and another* in relation to the nature of states' obligations to ensure access to medicines for their people. First, the paper discusses the facts of this case and the decision reached by the court. It then critically evaluates the decision based on three important issues - access to medicines as a human right, patent versus human rights and the nature of state's obligations in relation to access to medicines. The paper concludes by pointing out lessons African government should learn from this case.

1.1 Facts of the case

The petitioners in this case were all HIV positive adults, who had been living with HIV for periods ranging between eight and 19 years, who, with the exception of the second petitioner, had been on generic anti-retroviral drugs (ARVs) for about ten years. The first petitioner claims that she received her medication free of charge from *Medicines Sans Frontieres* (MSF) which operated a treatment programme in conjunction with the government of Kenya. The second petitioner, though HIV positive, not on ARV, but had a five-year old son who was HIV positive and on first line ARV, which he received free of charge from the MSF programme. . The third petitioner had been living with HIV/AIDS for about eight years and received ARVs free of charge from MSF programme. All the petitioners were unemployed and could not personally afford to pay for their ARVs.

³ World Trade Organization, Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WTO Doc No WT/MIN(01)/DEC/2 (2001). This seven-paragraph Declaration contains a number of important statements including the clarification on the use of flexibilities such as compulsory licensing, parallel importation and others.

The petitioners submitted that they have continued to receive their drugs free of charge by virtue of the Industrial Property Act⁴ which permits the importation of generic drugs. All of them were on first line ARV treatment combination of Stavudine (3TC), Zidovudine (AZT) and Nevirapine (NVP)-two tablets per day. They challenged the constitutionality of sections 2, 33, and 34 of the Anti-Counterfeit Act.⁵ The petitioners

⁴ Industrial Property Act 3 of 2001.

⁵ Anti-Counterfeit Act of 2008 **Section 2**. In this Act, unless the context otherwise requires—

“Agency” means the Anti-Counterfeit Agency established under section 3;

“Commissioner” shall have the meaning assigned to it under the Kenya Revenue Authority Act (Cap. 469);

“complainant” means a person, institution, government agency or state corporation entitled to lay a complaint under section 33 (1), or who has laid such a complaint;

“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 colourable 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 licence;

(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 mislabelling 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;

Section 33. (1) Any holder of an intellectual property right, his successor in title, licensee or agent may, in respect of any protected goods, where he has reasonable cause to suspect that an offence under section 32 has been or is being committed, or is likely to be committed, by any person, lay a complaint with the Executive Director.

(2) The complainant shall furnish, to the satisfaction of the Executive Director, such information and particulars, as may be prescribed, to the effect that the goods with reference to which that offence has allegedly been, or is being, or is likely to be, committed, prima facie are counterfeit goods.

(3) Where the Executive Director is reasonably satisfied—

(a) that the complainant is a person entitled to lay a complaint under subsection (1); and

(b) that—

(i) the goods claimed to be protected goods, prima facie are protected goods; and

(ii) the intellectual property right, the subject matter of which is alleged to have been applied to the offending goods, prima facie subsists; and

(c) that the suspicion on which the complaint is based appears to be reasonable in the circumstances, the Executive Director shall cause appropriate steps to be taken in accordance with section 23 (1).

(4) The preceding provisions of this section shall not preclude an inspector from taking any appropriate steps on his own initiative in relation to any act or conduct believed or suspected to be an act of dealing in counterfeit goods, provided the provisions of this Act are complied with.

(5) Nothing in this section shall preclude the Executive Director from causing appropriate steps to be taken in accordance with section 23 (1) in the event of an infringement of an intellectual property right for which no complaint has been lodged by the holder thereof in accordance with subsection (1) of this section.

Section 34. (1) The owner of an intellectual property right, who has valid grounds for suspecting that the importation of counterfeit goods may take place, may apply to the Commissioner in the prescribed manner to seize and detain all suspected counterfeit goods which are—

(a) goods featuring, bearing, embodying or incorporating the subject matter of that intellectual

- property right or to which the subject matter of that right has been applied; and
- (b) into or enter Kenya during the period specified in the application: Provided that the period may not extend beyond the last day of the period for which that intellectual property right subsists.
- (2) For purposes of sub-section (1), the applicant may furnish to the Commissioner—
- (a) a specimen of the goods to which the subject matter of his relevant intellectual property right relates;
- (b) sufficient information and particulars as to—
- (i) the subsistence and extent of that intellectual property right; and
- (ii) his title to that right.
- (3) The Commissioner shall consider and deal with an application under sub-section (1) within three working days and may grant the application if satisfied on reasonable grounds that—
- (a) the goods claimed to be protected are prima facie protected goods;
- (b) the intellectual property right, the subject matter of which relates to the protected goods, prima facie subsists; and
- (c) the applicant prima facie is the owner of that intellectual property right.
- (4) When an application made under subsection (1) has been granted and notice thereof given under subsection (5), the counterfeit goods of the type with reference to which that application was made (hereafter called the stipulated goods), or suspected on reasonable grounds to be stipulated goods, and imported into or entering Kenya from time to time during the period determined by the Commissioner, which may be shorter than the period applied for, may be seized and detained by the customs authorities in accordance with the East African Community Customs Management Act, 2005 subject to subsections (6) and (7).
- (5) The Commissioner shall, by notice in writing, inform the applicant whether the application has been granted or not, and—(a) if granted, state the period during which any stipulated goods being imported into or entering Kenya will be made subject to seizure and become subject to detention under subsection (4);
- (b) if not granted, state the reasons for refusal to be granted.
- (6) For purposes of acting under subsection (4) in relation to goods that are stipulated goods or suspected on reasonable grounds to be stipulated goods—
- (a) an authorized customs officer shall seize the counterfeit goods or alleged or suspected counterfeit goods, in accordance with subsection (1) or (4);
- (b) the following provisions will apply mutatis mutandis in relation to an authorized customs officer—
- (i) the provisions in accordance with or subject to which the powers contemplated in section 33 (4) may be exercised by an inspector so acting on his own initiative;
- (ii) the provisions by which any other power or any right, function, duty, obligation, exemption, indemnity or liability is conferred or imposed on an inspector so acting: Provided that the Minister, at the request of the Minister for the time being responsible for finance acting on the recommendation of the Commissioner, may, by notice in the Gazette, exempt an authorized customs officer from any of the provisions made applicable by this paragraph if satisfied that there are suitable and appropriate alternative arrangements made by or under the Customs Management Act, 2005 that cover the purpose of the provision from which exemption is sought.
- (7) Any person who suffers damage or loss caused by wrongful seizure, removal or detention of goods alleged to be counterfeit goods pursuant to an application made to the Commissioner shall be entitled to claim compensation for the damage or loss suffered by him against the applicant:
- Provided that compensation shall only be paid where the application for seizure and detention was false or negligent or made in bad faith.
- (8) The provisions of this Act shall not be construed so as to render the customs authority or any of its staff or agents liable for—
- (a) any failure to detect or seize stipulated goods;
- (b) the inadvertent release of any such goods; or
- (c) any action taken in good faith in respect of such goods.
- (9) For purposes of this section, “customs authority” means the Kenya Revenue Authority established under the Kenya Revenue Authority Act (Cap. 469).

contended that the impugned provisions were inconsistent with the provisions of the Kenyan Constitution as they potentially hindered access to life-saving medications for HIV positive persons. In particular, the petitioners contended that the Anti-Counterfeit Act will have negative effects on the manufacturing and accessibility of cheaper generics drugs, thereby infringing their rights to life, dignity and health guaranteed under articles 26(1), 28 and 43 of the Constitution of Kenya.⁶ The petitioners then asked the court for the following orders:

- (1) A declaration that the fundamental rights to life, dignity and health guaranteed under articles 26, 28 and 43 of the Kenyan Constitution encompass the right to affordable and accessible life-saving medications, including generic drugs;
- (2) A declaration that in so far as the Anti-Counterfeit Act limits access to essential and affordable drugs and medicines, including generic drugs for HIV/AIDS, it constitutes an infringement of the petitioners' rights to life, dignity and health all guaranteed under articles 26, 28 and 43 of the Kenya Constitution.
- (3) A declaration that the enforcement of the Anti-Counterfeit Act in so far as it affected access to affordable and essential drugs and medications, particularly generic medicines, was a breach of the petitioners' rights to life, dignity and health as guaranteed under articles 26(1), 28 and 43 of the Kenyan Constitution.
- (4) Any further orders, directions and declarations that the court may wish to make.⁷

During the pendency of this case, a non-governmental organisation, AIDS Law Project, was joined as an interested party, while the United Nations (UN) Special Rapporteur on the Right to the Highest Attainable Standard of Health was admitted as an amicus.

1.2 Decision

After reviewing the evidence before it and listening to the arguments of lawyers, the court found that sections 2, 32 and 34 of the Anti-Counterfeit Act were inconsistent with articles 26(1), 28 and 43 of the Kenyan Constitution. The court further found that the Anti-Counterfeit Act threatened to limit access to affordable and essential drugs and medicines, including generic medicines for HIV and AIDS. According to the court, the provisions of the Act would seem to have defined 'counterfeit' broadly such that it may encapsulate generic medicines. This is not only misleading but also dangerous as it may lead to a situation where generic medicines are classified as counterfeit and therefore

⁶ Article 26(1)(1) Every person has the right to life,

Article 28 Every person has inherent dignity and the right to have that dignity respected and protected,

Article 43(1) Every person has the right—

(a) to the highest attainable standard of health, which includes the right to health care services, including reproductive health care;

(b) to accessible and adequate housing, and to reasonable standards of sanitation;

⁷ *PA.O and others v Attorney General and another* para 2.

subject to criminalisation. The corollary of this is limited access to cheaper life-saving medicines. The court further reasoned that though the government may have a genuine intention to protect the public from the menace of substandard drugs, such an intention must be balanced with the rights of the citizens. The court advised that it was 'incumbent on the states to reconsider the provision of section 2 of the Anti-Counterfeit Act along its constitutional obligation to ensure that citizens have access to the highest attainable standard of health. . .'⁸

2 HIV/AIDS SITUATION IN KENYA

Before going into the analysis of the decision of this case, it is important to understand the context in which the decision was made by examining the HIV/AIDS situation in Kenya. This will provide an important background to the filing of the case and the decision reached by the court. In the early years of the HIV/AIDS epidemic around 1983 to 1985 only 26 cases of HIV/AIDS infections were reported in Kenya.⁹ By the end of 1987 this has increased to about 288 cases with prevalence highest among sex workers.¹⁰ Over the years the Kenyan government has taken various steps to respond to the HIV/AIDS epidemic. The government's response to the epidemic is coordinated by the National AIDS Control Council (NACC) which was established in 1999. At the end of 2011 an estimated 1.6 million people were said to be living with HIV in Kenya. Of this figure, an estimated 500,000 people (about 75%) in need of HIV treatment were receiving it.¹¹ This is a significant achievement for the government as compared to other countries in Africa. It should be noted that one of the key pillars of the Kenya National HIV and AIDS Strategic Plan for 2010-2013 (KNASP III) is the provision of cost-effective prevention, treatment, care and support services, informed by an engendered rights-based approach, to realise universal access. Towards this goal government has laid emphasis on improving the coverage of antiretroviral therapy to reach rural communities and scaling-up services in relation to the prevention of mother-to-child-transmission of HIV.

With regard to prevention of mother-to-child transmission of HIV, an estimated 69% of HIV-positive pregnant women were said to be receiving treatment in 2011.¹² Since 2000 prevention of mother-to-child transmission services has increased greatly. Indeed, the treatment programme of the Kenyan government has improved considerably over the years. It is currently estimated that there are now more than 3,397 health facilities offering PMTCT services in country.¹³ When it first started few years back, the number of people receiving treatment, like in many other African

⁸ *PA.O and others v Attorney General and another* para 88.

⁹ AIDS Newsletter (1987) 'Military service in Kenya: AIDS risk', Item 14, 15th January 1987.

¹⁰ AIDS Newsletter (1987) 'Africa', Item 181, 23rd March 1987.

¹¹ Kenya National AIDS Control Council 'Kenya AIDS epidemic update report' Kenya National AIDS Control Council 2012.

¹² *Ibid.*

¹³ United Nations General Assembly Special Session on HIV and AIDS (UNGASS 2010) Country Report for Kenya (Kenya National AIDS Control Council, NACC (2010).

countries, was very low. For instance as at 2003 only 5% of those in need of HIV treatment was receiving it.¹⁴ However, over the last few years the government has renewed its commitment to combating the epidemic and has been able to secure support from various donor institutions and some developed countries to scale up access to HIV treatment significantly. In 2006 the Kenyan government announced that antiretroviral drugs will be provided free for those in need at public hospitals and health centres.¹⁵ This was a significant move given that majority of those in need of treatment during the time lacked access. The development has in turn led to a drastic reduction (about 50%) in number of people dying from HIV-related complications.

While this modest progress is commendable, the Kenyan HIV treatment programme continues to face series of challenges. In particular, universal access to life-saving medications for people in rural areas is hindered by HIV-related stigma and discrimination and incoherent policy formulation and implementation. Moreover, access to treatment for vulnerable groups such as children and sex workers is still poor. It is estimated that only 31% of children in need of treatment are receiving it.¹⁶ Perhaps one of the biggest concerns relating to access to HIV treatment in Kenya is the weak healthcare system often as a result of the shoe-string budget allocation by government to the health sector.¹⁷ It should be noted that about 80% of the resources for HIV treatment in Kenya come from donor organisations and developed countries.¹⁸ This clearly makes the country highly vulnerable in terms of ensuring the sustainability of the HIV treatment programme. In recent times, allocation by the Kenyan government to the health sector has hovered around 5-6%, while specific spending on HIV has continued to decrease below 25% since 2007.¹⁹ This is a major cause for concern and would seem to imply that the government is taking a retrogressive step towards the realisation of the right to health. It would be recalled that in 2001 during the Abuja Declaration, African governments committed themselves to allocating at least 15% of their annual budgetary allocations to the health sector.²⁰

3 ACCESS TO MEDICINES AS A HUMAN RIGHT

One of the issues raised in this case relates to the importance of access to medicine as a fundamental human right. It is now widely agreed that access to medicines constitute an integral part of the right to health.²¹ During the UN General Assembly Special Session on

¹⁴ WHO/UNAIDS/UNICEF *Towards Universal Access: Scaling up priority HIV/AIDS Intervention in the Health Sector* (Geneva: WHO, 2007)

¹⁵ BBC News 'Kenya to provide free AIDS Drugs' available at <http://news.bbc.co.uk/2/hi/africa/5040240.stm> (reported on 2 June 2006).

¹⁶ UNAIDS 'Report On The Global AIDS Epidemic' (Geneva, UNAIDS, 2012)

¹⁷ *Ibid.*

¹⁸ *Ibid.*

¹⁹ *Ibid.*

²⁰ African Summit on HIV/AIDS, Tuberculosis and other Related Infectious Diseases, Abuja-Nigeria April 24-27 2001 OAU/SPS/ABUJA/3.

²¹ See for instance, Durojaye E 'Advancing gender equity in access to HIV Treatment through the Protocol to the African Charter on the Rights of Women (2006) *African Human Rights Law Journal* 187; see also,

HIV& AIDS in 2001,²² the international community reaffirmed that access to medicine, particularly HIV medicines, for those in need, constitutes a fundamental human right. This position was echoed by the UN General Assembly during the Political Commitment in 2011²³ where the international community committed to ensuring access to HIV medicines to 15 million people by 2015.

It should be noted that the right to health is explicitly guaranteed in numerous human rights instruments such as article 12 of the International Covenant on Economic, Social and Cultural Rights²⁴ (ICESCR), article 12 of the Convention on Elimination of All Forms of Discrimination against Women²⁵ (CEDAW) and article 24 of the Convention on the Rights of the Child²⁶ (CRC). By far the most authoritative provision on the right to health is found in article 12 of the ICESCR.²⁷ It guarantees the right of the highest attainable standard of health for everyone. In addition, article 12 (2) of the same provision recognises the relevance of the underlining determinant of the right to health such as access to clean environment, child and maternal health, and safe drinking water.

The Committee on Economic, Social and Cultural Rights (CESCR) has explained that the right to health includes both freedoms and entitlements.²⁸ According to the Committee, ‘freedoms’ implies that states should not interfere with individuals’ autonomy to consent to medical treatments, while ‘entitlements’ imposes obligations on states to ensure the provision of health facilities, goods and services, including essential medicines. The CESCR has further explained that access to essential medicines constitute a minimum core of the right to health. This implies that states parties to the Covenant cannot on the excuse of lack of resources fail to make available life-saving medications for those in need. This will not only amount to the violation of the right to health, but also infringe the right to life. Indeed, the CESCR in its General Comment 14 has explained that the enjoyment of the right to health is dependent on other human

Hongerzeil HV *et al* ‘Is Access to essential medicines as part of the fulfillment of the right to health enforceable through the courts?’ (2006) 360 *Lancet* 305.

²² UN General Assembly Special Session on HIV/AIDS Resolution A/S-26/L2 June 2001 para 15.

²³ UN General Assembly Session 2011.

²⁴ International Covenant on Economic, Social and Cultural Rights, U.N. Doc.A/6316 (1966).

²⁵ Convention on Elimination of All Forms of Discrimination against Women (CEDAW)G.A. res. 34/180, 34 U.N. GAOR Supp. (No. 46) at 193, U.N. Doc. A/34/46, *entered into force* Sept. 3, 1981.

²⁶ International Convention on the Rights of the Child (CRC), U.N. Doc. A/RES/44/25, 1989.

²⁷ International Covenant on Economic, Social and Cultural Rights, Article 12 (1) ‘The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. (2) The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

- (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
- (b) The improvement of all aspects of environmental and industrial hygiene;
- (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
- (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

²⁸ UN Committee on Economic, Social and Cultural Rights (CESCR) General Comment No 14: The Right to the Highest Attainable Standard of Health, UN Doc E/C/12/2000/4.

rights, such as rights to human dignity, privacy, non-discrimination and life.²⁹ Other commentators have echoed this view. For instance, Yamin has argued that the denial of life-saving medications for people living with HIV will constitute the violation of the right to life.³⁰

At the regional level, the right to health is guaranteed in the African Charter on Human and Peoples' Rights³¹ (African Charter).³² The wording of that provision is almost similar to that of article 12 of the ICESCR. Also, article 14 of the Protocol to the African Charter on the Rights of Women³³ (African Women's Protocol) explicitly guarantees the right to health, including sexual and reproductive health and rights of women.³⁴ Article 14 is one of the most detailed provisions on the right to health of women, including sexual and reproductive health. The provision for the first time affirms sexual and reproductive health as human rights, and provides for the autonomy of women to seek information and services relating to contraception, enjoy safe maternal health and seek abortion services on certain grounds.

²⁹ Ibid.

³⁰ Yamin AE 'Not Just a tragedy: access to medications as a right under international law' 21 *Boston University International Law Journal* 325 -371. See also Durojaye E 'Compulsory Licensing and Access to medicines in post Doha Era: What hope for Africa? (2008) 51 *Netherlands International Law Review* 33-72; Hongenzeit et al note 21 above.

³¹ African Charter on Human and Peoples' Rights (Adopted 27 June 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force 21 October 1986).

³² African Charter on Human and Peoples' Rights, Article 16(1) Every individual shall have the right to enjoy the best attainable state of physical and mental health. 2. States Parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.

³³ Protocol to the African Charter on the Rights of Women. (Adopted by the 2nd Ordinary Session of the Assembly of the Union, Maputo, CAB/LEG/66.6 (Sept. 13, 2000) *entered into force* 25 November 2005.)

³⁴ Protocol to the African Charter on the Rights of Women Article 14: Health and Reproductive Rights (1) States Parties shall ensure that the right to health of women, including sexual and reproductive health is respected and promoted. This includes:

- a) the right to control their fertility;
- b) the right to decide whether to have children, the number of children and the spacing of children;
- c) the right to choose any method of contraception;
- d) the right to self-protection and to be protected against sexually transmitted infections, including HIV/AIDS;
- e) the right to be informed on one's health status and on the health status of one's partner, particularly if affected with sexually transmitted infections, including HIV/AIDS, in accordance with internationally recognised standards and best practices;
- g) the right to have family planning education.

2. States Parties shall take all appropriate measures to:

- a) provide adequate, affordable and accessible health services, including information, education and communication programmes to women especially those in rural areas;
- b) establish and strengthen existing pre-natal, delivery and post-natal health and nutritional services for women during pregnancy and while they are breast-feeding;
- c) protect the reproductive rights of women by authorising medical abortion in cases of sexual assault, rape, incest, and where the continued pregnancy endangers the mental and physical health of the mother or the life of the mother or the foetus.

The African Commission on Human and Peoples' Rights (African Commission) in *Purohit and Moore v The Gambia*³⁵ has explained that the provision of article 16 of the African Charter imposes obligation on states to ensure that access to health-related goods and services (including access to medicines) is guaranteed to all without discrimination. In addition, the African Commission has noted that realising access to life-saving medications is a human rights issue and thus urges states to take necessary steps to facilitate access to life-saving medications for their citizens. It should be noted that Kenya has ratified most of the human rights instruments mentioned above. Therefore, the country is obligated to fulfil the provisions of these instruments.

Despite these copious provisions on the right to health at the international and regional levels, access to medicines, particularly life-saving medications in the context of HIV/AIDS has remained a great challenge in many African countries, including Kenya. While it should be noted that the number of people receiving HIV treatment has improved considerably compared to 10 years ago, a significant number of people still lack access to life-saving medication. Currently, it is estimated that eight million people out of 15 million in need of HIV treatment across the world, are receiving it.³⁶ About six million of those receiving treatment are from Africa.³⁷ This is a significant improvement compared to 2004 when only about 440,000 people were said to be receiving treatment across the world.³⁸ The improvement in the number of people receiving treatment across the world particularly in Africa is attributed to donor institutions and governments, such as the Bill and Melinda Gates Foundation,³⁹ Clinton Foundation,⁴⁰ the Global Fund to Fight AIDS, Tuberculosis and Malaria⁴¹ and the United States President's Emergency Plan for AIDS Relief (PEPFAR).⁴²

While the above developments are commendable, challenges remain regarding the scaling-up of HIV treatments in Africa. Indeed, disparities exist across the region as regards the number of people receiving treatment, particularly in relation to the prevention of mother-to-child transmission of HIV. While many of the countries in the southern part of the region, such as, Botswana, Namibia and South Africa have achieved universal access as regards prevention of mother-to-child transmission, their counterparts in other sub-regions such as West Africa are still lagging behind.⁴³ The revised Guideline 6 of the International Guidelines on HIV/AIDS and Human Rights⁴⁴

³⁵*Purohit and Moore v. The Gambia* African Communication No. 241/2001 (2003).

³⁶ UNAIDS *Together we Will End AIDS* (Geneva UNAIDS 2012) 9 (UNAIDS / JC2296E)

³⁷ Ibid.

³⁸ UNAIDS/WHO *AIDS Epidemic Update* (Geneva, UNAIDS 2004) 6.

³⁹ Bill and Melinda Gates Foundation (www.gatesfoundation.org/)

⁴⁰ Clinton Foundation (www.clintonfoundation.org/)

⁴¹ The Global Fund to Fight AIDS, Tuberculosis and Malaria (www.theglobalfund.org/).

⁴² The United States President's Emergency Plan for AIDS Relief (PEPFAR) (www.pepfar.gov/).

⁴³ UNAIDS '*Global AIDS Epidemic Report*' (Geneva, UNAIDS 2010) 99.

⁴⁴ International Guidelines on HIV/AIDS and Human Rights (U.N.C.H.R. res. 1997/33, U.N. Doc. E/CN.4/1997/150 (1997)).

enjoin states to review and, where necessary, amend or adopt laws, policies, programmes and plans to realise universal and equal access to medicines...'.⁴⁵

It should be noted that the bulk of HIV medicines supplied to the Kenyan treatment programme are generic drugs rather than patented,⁴⁶ which account for the wide coverage of the treatment programme. Therefore, the introduction of the Anti-Counterfeit Act constitutes a major threat to access to HIV treatment and may undermine the rights of people living with HIV in Kenya. As rightly pointed out by the court, a state is under obligations to respect, protect and fulfil the right to health, including access to medicines for its citizens. A violation of the obligation to respect will occur if a state adopts any policy or measure, which may prevent its citizens from realising this right.

In one of its resolutions on access to medicine in Africa, the African Commission has enjoined states to refrain from taking steps that will hinder access to medicines for their citizens.⁴⁷ Also, the African Commission notes that states should always give priority to their obligations with respect to the right to health above any other considerations. The African Commission particularly emphasizes that African government must refrain from 'implementing intellectual property policies that do not take full advantage of all flexibilities in the WTO Agreement on Trade-Related Aspects of Intellectual property Rights (TRIPS), that promote access to affordable medicines, including "TRIPS-Plus" trade agreement'.⁴⁸

The petitioners in *P.A.O* claimed that the Anti-Counterfeit Act threatened their rights to life, dignity and health. Besides the problem of prevention of mother-to-child transmission of HIV, there are also concerns that some of the people on treatment in Kenya might develop resistance to first line treatment. The implication of this is that sooner or later, most people will have to move to second line treatment. These drugs are more expensive than those for the first line treatment due to the fact that most of them (second line drugs) are patented. This underlines the importance of ensuring access to generic medicines for people living with HIV. The petitioners in the *P.A.O* case had argued along this line and the court upheld the argument. By so doing, the court would seem to be suggesting that the Kenyan government would need to take more drastic steps to remove barriers to cheaper medications for its citizens. This is consistent with the government's obligations to promote and protect the right to health.

⁴⁵ International Guidelines on HIV and Human Rights, Guideline 6 (as revised in 2002): 'States should enact legislation to provide for the regulation of HIV-related goods, services and information, so as to ensure widespread availability of quality prevention measures and services, adequate HIV prevention and care information, and safe and effective medication at an affordable price. States should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of quality goods, services and information for HIV prevention, treatment, care and support, including antiretroviral and other safe and effective medicines, diagnostics and related technologies for preventive, curative and palliative care of HIV and related opportunistic infections and conditions. States should take such measures at both the domestic and international levels, with particular attention to vulnerable individuals and populations.'

⁴⁶ As above note 13.

⁴⁷ African Commission on Human and Peoples' Rights ACHPR/Res.141 (XXXXIII) 08: Resolution on Access to Health and needed Medicines in Africa.

⁴⁸ Ibid.

4 INTELLECTUAL PROPERTY RIGHTS VERSUS HUMAN RIGHTS

For so many years, the debate has raged on as to whether or not patent rights constitute barriers to access to HIV treatment in developing countries. On the one hand, pharmaceutical companies have argued that there is no correlation between patent rights and access to treatment, noting that even if drugs were not patented in the region, access to treatment will remain a challenge due to poor facilities, dearth of skilled health personnel, lack of resources and corruption. In addition, they have argued that manufacturing of drugs is capital intensive and requires long years of investment in research and development (R&D).⁴⁹ Therefore, they submit that unless patent is guaranteed for manufactured drugs further research into new drugs will be impossible due to lack of incentive.⁵⁰

On the other hand, people living with HIV and commentators have expressed the views that patent rights, particularly on pharmaceutical products, constitute great barriers to life-saving medications in Africa.⁵¹ This argument would seem to have been supported by a study carried out by the Commission on Intellectual Property Rights⁵² where it was found that patent rights on pharmaceutical products often lead to high cost of drugs and do constitute barriers to access to treatment in poor regions.⁵³ While it is true that patent protection is by no means the only barrier to access to medicines, undoubtedly patents play a crucial, if not determinant, role in limiting access to life-saving medications in the context of HIV.⁵⁴ In response to pharmaceutical companies' argument that patent rights encourages R&D, it has been noted that sub-Saharan Africa merely accounts for about 2 per cent of total profits derived from patented drugs and that if there were no patent protection in Africa, and no sales by pharmaceutical companies, their profits from drugs will by no means be affected.⁵⁵ Moreover, it has been contended that patents do not necessarily promote R & D⁵⁶ and that funding for R&D in some developed countries such as America are borne by public institutions.⁵⁷ Therefore,

⁴⁹ International Intellectual Property Institute (IPI), *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa* (Washington, DC, IPI 2000) p. 24.

⁵⁰ Ibid

⁵¹ See Osewe P *et al* *Improving Access to HIV Medicines in Africa: Trade Related Aspect of Intellectual Property Rights Flexibilities* (2008); see also, Berger J 'Tripping over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity', 17 (2002) *Connecticut Journal of International Law* 157; Hestermeyer, H *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford: Oxford University Press 2007) 154.

⁵² See Commission on Intellectual Property Rights (independent commission set up by British government), Final Report, September 2002, available at <www.iprcommission.org> (Accessed on 3 September 2012).

⁵³ Berger note 51 above; Durojaye note 30 above.

⁵⁴ See Osewe *et al* note 51 above.

⁵⁵ See for instance, Boulet, P. *et al.*, *Drug Patents under the Spotlight: Sharing Practical Knowledge about Pharmaceutical Patents* (Geneva, MSF 2003) 6.

⁵⁶ WHO Commission on Intellectual Property Rights, 'Innovation and Public Health, Framework paper', July 2004, available at <www.who.int/intellectualproperty/documents/thereport/CIPIH23032006.pdf> (accessed on 4 September 2012)

⁵⁷ Foreman M. *et al*, *Beyond Our Means? The Cost of Treating HIV/AIDS in the Developing Countries* (London, Panos Institute 2000) at 1.

it is misleading to argue that R&D promote costs necessitate patent rights on life-saving drugs.

It must be recalled that during the negotiation for the World Trade Organisation's (WTO) agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS),⁵⁸ developing countries had expressed scepticism regarding a need for strong intellectual property regime on pharmaceutical products. This is because many of the developing and least developed countries lack the capacity to manufacture pharmaceutical products. Eventually, however, developing and least developed countries were strongly persuaded by developed countries based on the promise that they(developing and least developed countries) will receive subsidies on agricultural products.

It should be noted that despite the strong intellectual property regime imposed by the TRIPS Agreement, member states have some latitudes to make use of the flexibilities contained therein. Some of which include compulsory licencing, parallel importation and bolar exception.⁵⁹ However, the major challenge with the use of the flexibilities in the TRIPS Agreement has remained stiff opposition from developed countries and pharmaceutical companies. In most cases developed countries backed by the United States have argued that the use of compulsory licensing to facilitate the manufacture of generic drugs will not only erode patent rights of pharmaceutical companies, but may also encourage manufacturing of substandard drugs.⁶⁰ Attempts by countries, such as, South Africa, Thailand and India to invoke the flexibilities in the TRIPS agreement have all been met with opposition and threats from developed countries, particularly the United States.⁶¹ Kenya is a member of the WTO and in line with its obligation under the TRIPS Agreement enacted the Intellectual Property Act.

⁵⁸ The TRIPS Agreement was part of the Final Act establishing the WTO commonly referred to as the 'Marrakech Agreement', attached as Annex 1C to the WTO Agreement.

⁵⁹ (i) Compulsory licensing-refers to the mechanism used by public authorities to authorize use of a patent-protected invention by the government or third parties without the consent of the patent-holder. Usually compensation is paid to the patent holder.

(ii) Parallel importation- refers to a situation whereby a country with limited resources can sometimes afford more of a patented medicine by purchasing it abroad at a lower price and importing it, rather than buying it directly in its domestic market at the higher price.

(iii) Bolar exception- This permits the use of a patented invention without authorization from the patent owner in order to obtain marketing approval of a generic product before the patent expires. This allows a generic product to enter the market more quickly after patent expiry, which in turn facilitates access to cheaper medicines.

⁶⁰ See Durojaye E *TRIPS, Human Rights and Access to Medicines in Africa: A Post Doha Analysis* (VDM Verlag Dr. Müller Press 2010).

⁶¹ The case of the 39 pharmaceutical companies that sued the South African government for introducing a law that permits the use of compulsory licensing and parallel imports in 1998, see *Pharmaceutical Manufacturers' Association of South Africa v President of the Republic of South Africa*, Case No 4183 of 1998. The Thai government has also been challenged and threatened by Abbot, one of the big pharmaceutical companies for invoking the use of compulsory licensing to facilitate access to a cancer drugs for which Abbot owed the patent. More recently, Indian government has been challenged by Novartis for adopting a strict requirement for renewal of patent in its recent patent law. The Supreme Court of India has rejected the patent application filed by Novartis. See *Novartis v Union of India & Others* Supreme Court of India Civil Appeal No. 2706-2716 of 2013, available at <http://supremecourtindia.nic.in/outtoday/patent.pdf>. (accessed 22 April 2013).

While the Act recognises patent rights on medicines, it empowers the Kenyan government to invoke some measures such as parallel importation and compulsory licensing to facilitate access to cheaper drugs for the citizens.

Experience has shown that generic drugs cost far less than patented drugs and they are accessible and affordable for majority of people in need. A study has shown that generic drugs cost 10 times less than patented drugs.⁶² This is a clear indication that the invocation of the flexibilities in the TRIPS Agreement in order to facilitate access to generic drugs is consistent with the realisation of the right to health as guaranteed under the international human rights law. It would be recalled that during the Ministerial Council Meeting of WTO in 2001 (Doha Declaration), it was affirmed that member states have the right to invoke the flexibilities in the TRIPS Agreement in order to address public health emergency.⁶³

More importantly, it was affirmed that member states are at liberty to decide when they can use compulsory licensing in order to facilitate access to cheaper medicines for their citizens. While it remains debatable whether the Doha Declaration constitutes a binding obligation on states, it is incontestable that the Declaration imposes moral obligations on member states of WTO to ensure that the TRIPS Agreement is implemented in a way that advances public health.

It is sad to note that more than a decade after the Doha Declaration, developed countries and pharmaceutical companies have remained stumbling blocks to availability, accessibility and affordability of life-saving medications, particularly in the context of HIV/AIDS. Worse still, some developed countries, including members of the European Union (EU), have resorted to bullying tactics with a view to pressurising some developing and least developed countries to adopt stricter intellectual property rights regimes than envisaged by the TRIPS Agreement. This is commonly referred to as TRIPS-plus. One of such approaches is to request developing or least developed countries to enact anti-counterfeit laws to deal with substandard drugs. The facts of the *P.A.O* case bring to the fore once more this contentious issue. It should be noted that the Kenyan government through the Intellectual Property Act has incorporated some of the flexibilities in the TRIPS agreement into its domestic law. This piece of legislation permits Kenyan government to invoke the use of compulsory licensing and parallel importation in order to facilitate access to cheaper generic medicine for those in need. This is a welcome development and would seem to portray the Kenyan government as willing to advance the right to health of its citizens.

While it is agreed that the issue of substandard drugs is a challenge in many African countries and needs to be addressed, the problem, however, is that the so-called anti-counterfeit laws being proposed by developed countries tend to give a broad definition of what amounts to counterfeit drugs. Indeed, some of these laws define

⁶² WTO, Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WTO Doc. No. WT/MIN(01)/DEC/2 (2001) para 4.

⁶³ T Heon E.F.M *The Global Politics of Pharmaceutical Monopoly Power: Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (Netherlands: AMB Publishers, 2009) 25.

counterfeit drugs to include generic medicines. A good example is the Kenya Anti-Counterfeit Act,⁶⁴ which was the bone of contention in this case. According to section 2 of the Act, 'counterfeit' is defined to mean (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';⁶⁵ (d) 'in relation to medicine, the deliberate and fraudulent mislabelling 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.'⁶⁶

The petitioners in this case argued that this definition is too broad and would seem to have subsumed generic medicines under the term 'counterfeit'. It was therefore argued that such a broad definition is not only misleading, but also capable of limiting access to life-saving medications to those in need. As noted earlier, generic drugs are cheaper than patented medicines and given the fact that most of the HIV drugs used in Kenya are generic rather than patented, the provisions of the Anti-Counterfeit Act were likely to be counterproductive. More importantly, the petitioners contended that this provision would infringe the rights to life, dignity and health guaranteed under the Kenyan Constitution.⁶⁷

In agreeing with the petitioners, the judge held that the language of the Anti-Counterfeit Act would seem to be overly broad and amount to a sweeping generalisation by classifying generic drugs as counterfeits. Using the rights-based approach, the judge reasons that the Kenyan government is obligated under international human rights law and the national Constitution to respect the rights to life, dignity, and health of its citizens. This obligation requires the Kenyan government to refrain from taking any steps, including the enactment of any law that will hinder access to life-saving medications for the people. The court also noted that while it is desirable to protect the public from counterfeit goods, and preserve the right of pharmaceutical companies to enjoy patent rights, this must be weighed against a state's obligation not to interfere with the enjoyment of the rights of its citizens. According to the court:

"the rights to life, dignity and health of people like the petitioners who are infected with the HIV virus [sic] cannot be secured by a vague proviso in a situation where those charged with the responsibility of enforcement of the law may not have a clear understanding of the difference between generic and counterfeit medicine."⁶⁸

To buttress this argument, the court relied on the interpretation provided by the Committee on Economic, Social and Cultural Rights (CESCR) in its General Comment 14⁶⁹ on the right to health, and General Comment 17⁷⁰ relating to the interpretation of

⁶⁴ Kenya Anti-Counterfeit Act 2008.

⁶⁵ Section 2(a) Kenya Anti-Counterfeit Act 2008.

⁶⁶ Section 2(d) Kenya Anti-Counterfeit Act 2008.

⁶⁷ The rights to life, dignity and health guaranteed under the Kenyan Constitution article 26.

⁶⁸ *PA.O and others v Attorney General and another* para 84.

⁶⁹ UN Committee on Economic, Social and Cultural Rights (CESCR) General Comment 14 note 28 above.

⁷⁰ UN Committee on Economic, Social and Cultural Rights (CESCR) General Comment 17 The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific,

article 15 (1) (c) of the ICESCR. According to the court, while it is agreed that intellectual property rights are recognised as human rights, the enjoyment of such rights must be balanced with the enjoyment of crucial rights such as rights to life, dignity and health.

More importantly, and as noted by the Committee on Economic, Social and Cultural Rights (CESCR) in its General Comment 17, while the enjoyment of intellectual property rights is ephemeral, human rights are inalienable, indivisible and limitless.⁷¹ The court further states that:

“It would be in violation of the state’s obligations to the petitioners with respect to their right to life and health to have included in legislation ambiguous provisions subject to the interpretation of intellectual property holders and customs officials when such provisions relate to access to medicines essential for the petitioners’ survival.”⁷²

There is a growing consensus at international law level that respect for human rights should supersede trade agreements including the TRIPS Agreement. This is bolstered by the argument that article 103 of the UN Charter provides that states’ obligations under other treaties should not conflict with their obligations under the Charter.⁷³ Given that the UN Charter is founded on the respect for human rights of all individuals, it can be argued that a state cannot assume any obligation under trade agreements, including the TRIPS Agreement that will be inconsistent with its obligation under the UN Charter. Furthermore, Forman has argued that states’ obligations with regard to ensuring access to medicines is of a higher threshold than obligations under trade agreements, including TRIPS, since the former will implicate the right to life which is regarded as the most fundamental of all human rights.⁷⁴ The UN Sub- Commission on Human Rights has noted that there is bound to be a conflict between the implementation of intellectual property rights agreements and human rights treaties.⁷⁵ It therefore urges states to ensure that their obligations to safeguard human rights are not sacrificed at the altar of trade agreements such as the TRIPS.

5 LESSONS FROM THE DECISION IN PAO CASE

The court’s decision in the *P.A.O* case has come at a time when many African countries, including Kenya, still struggle to realise access to medicines for their citizens. Perhaps with the exception of South Africa, many countries in Africa have not really taken seriously the issue of access to medicines as a fundamental human right. This is

literary or artistic production of which he or she is the author (article 15, paragraph 1 (c), of the Covenant) 12 January 2006, U.N Doc. E/C.12/GC/17, available at: <http://www.refworld.org/docid/441543594.html> [accessed 22 April 2013].

⁷¹ UN Committee on Economic, Social and Cultural Rights (CESCR) General Comment 17, para 2.

⁷² *PA.O and others v Attorney General and another* para 84.

⁷³ Charter of the United Nations, 26 June 1945 (entered into force 24 October 1945), *TS* 67(1946).

⁷⁴ Forman, L, ‘Trade Rules, Intellectual Property and the Right to Health’ (2007) 21 *Ethics and International Affairs* 337; see also, Cullet P, ‘Patents and Medicines: The Relationship between TRIPS and Human Rights to Health’, (2003) 79 *International Affairs* 140.

⁷⁵ UN Sub-Commission on the Promotion and Protection of Human Rights. “Globalization and its impact on the full enjoyment of all human rights.” Resolution 2001/5 (15 Aug 2001), UN Doc E/CN.4/Sub.2/Res/2001/5.

worrisome given that Africa remains home to the largest number of people living with HIV in the world. It would be recalled that in 2001 African governments declared HIV/AIDS a state of emergency in the region and called for concerted efforts to mitigate its impact on the continent.⁷⁶ While it is noted that few constitutions in Africa explicitly recognise the right to health, the fact that the right to health also intersects with other rights, such as, life, dignity and discrimination, makes it imperative for African governments to take the issue of access to medicines very seriously.⁷⁷ It is sad to note that despite the flexibilities contained in the TRIPS Agreement - affirmed during the Doha Declaration- very few African countries have made attempts to either incorporate these flexibilities in their national laws or even invoked them to facilitate access to generic medicines for their citizens.

One of the important lessons that can be learnt from this case is that it reaffirms the viability of litigation in advancing social rights and justice. Gloppen has argued that health rights litigation can be useful in holding a government accountable for its failure to realise the right to health within its jurisdiction.⁷⁸ Her argument is based on the fact that people and institutions entrusted with powers and responsibilities have the obligation to justify that those powers and responsibilities have been used appropriately. Hogerzeil *et al*⁷⁹ have similarly argued that 'Skilful litigation can help to ensure that governments fulfil their constitutional and international treaty obligations. Such assurances are especially valuable in countries in which social security systems are still being developed. Other commentators, such as, Pieterse, have noted that social rights litigation, including health rights litigation, has the potential of advancing social justice and redistributing wealth in society, particularly among the poor.'⁸⁰

A good example of a case where a government has been held accountable for its obligation to realise the right to health is the South African case of *Minister of Health and others v Treatment Action Campaign (TAC case)*.⁸¹ In that case, the South African Constitutional Court noted that the failure of the South African government to provide Nevirapine (NVP) widely in public care institutions for the purpose of preventing mother- to- child transmission of HIV amounts to a violation of the right to health as guaranteed in section 27 of the South African Constitution. This decision clearly exemplifies the point that the right to health imposes a positive obligation on a state to take appropriate measures and steps in order to ensure access to life-saving medication for its citizens. A point, which was reinstated in the *P.A.O* case when the court notes that the adoption of the Anti-Counterfeit Act by the Kenyan government would seem to be

⁷⁶ Abuja Declaration above note 20.

⁷⁷ See Viljoen F, *International human rights law in Africa* (Oxford University Press, 2007).

⁷⁸ Gloppen S, 'Litigating as a Strategy to Hold Government s Accountable for Implementing the Right to Health'(2008) 10 *Health and Human Rights* 21.

⁷⁹ Hogerzeil H V *et al* 'Is Right to Essential Medicines as part of the Fulfillment of the Right to Health Enforceable through the Curt?'(2006)368 *Lancet* 305.

⁸⁰ See Pieterse M 'The Potential of Socio-economic Rights Litigation for the Achievement of Social Justice:: Considering the example of Access to Medical Care in South African Prisons' (2006) 50 *Journal of African Law* 118; see also, M Heywood 'South Africa's Treatment Action Campaign: Combining Law and Social Mobilisation to Realise the Right to Health' (2009) 1 *Journal of Human Rights Practice* 24.

⁸¹ *Minister of Health v Treatment Action Campaign and Others* 2002 10 BCLR 1033 (CC).

inconsistent with its obligations to realise the rights to life, dignity and health of its citizens.

Another important lesson learnt from this case is that health rights litigation may be initiated by few individuals the outcome of the decision may impact positively on the lives of hundreds of people. From the fact of this case, it can be seen that the case was originally initiated by four petitioners but the outcome will no doubt benefit hundreds of Kenyans who are HIV positive and are qualified to be enrolled in the treatment programme. In other words, the outcome of social rights litigation goes beyond the original parties to the case but may have multiplier effects on the society as a whole, especially the vulnerable and marginalised groups. Affirming this point, Liebenberg has noted that litigating on socio-economic rights generally, and right to health in particular, has the potential of tangibly alleviating the suffering of vulnerable groups and ensuring them affirmative remedies that will satisfy their immediate vital needs within society.⁸²

A broad interpretation of *P.A.O* case would seem to suggest that the failure or reluctance of a government to invoke the flexibilities contained in the TRIPS Agreement to facilitate access to generic medicines for its citizens would amount to a violation of the obligation to safeguard the rights to health and life guaranteed in numerous human rights instruments. In the same vein, the recent development in some African countries where various forms of agreements, which impose stricter obligations than envisaged in the TRIPS Agreement (TRIPS plus) are being concluded, will also amount to a breach of the obligation to safeguard the rights to health and life under international human rights law. Article 66 of the TRIPS agreement read together with paragraph 7 of the Doha Declaration gives least developed countries in Africa the latitude not to be TRIPS compliant until 2016.⁸³ Unfortunately, however, some of these least developed countries in Africa are already adopting TRIPS-complaint legislation. Moreover, some African countries have been reluctant in invoking the flexibilities contained in the TRIPS to facilitate access to life-saving medications for their people. Osewe *et al* have noted that obstacles to the use of flexibilities in TRIPS in Africa are due to ignorance, lack of political will and poor or inefficient administrative structures.⁸⁴ The implication is that in these countries access to essential medicine maybe difficult. As pointed out earlier, the African Commission has urged African countries to live up to their obligations with regard to realising access to medicine for their citizens. In particular, the reasoning of the African Commission in the *Purohit*⁸⁵ case would seem to suggest that failure by African governments to provide access to medicines for vulnerable and marginalised groups such as people living with HIV would amount to a violation of the right to health

⁸² See S. Liebenberg, 'Needs, rights and transformation: adjudicating social rights' (2005) 8 *Center for Human Rights and Global Justice Working Paper* (Economic and Social Rights Series) 6–7.

⁸³ Many of these countries are from Africa they include Angola, Benin, Burkina Faso, Burundi, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, The Gambia, Guinea, Lesotho, Liberia, Malawi, Mauritania, Mozambique, Niger, Rwanda, Sierra Leone, Togo, Uganda, Tanzania, and Zambia

⁸⁴ Osewe *et al* above note 48, xxi.

⁸⁵ *Purohit v The Gambia* above note 35.

and constitute an act of discrimination contrary to articles 2 and 3 of the African Charter.

Despite the positive nature of litigation in advancing social justice, it is important to note that victory in the courtroom does not necessarily translate to better living conditions for the people. In other words, too much hope should not be placed on social rights litigation, including health rights litigation. Goppen and Roseman have indeed cautioned that while health rights litigation has the potential of addressing social injustice, too much reliance should not be placed on it in order to avoid abuses or what has been referred to as the 'epidemic of litigation'.⁸⁶ They made references to situations in Latin American countries where health rights litigation is being used constantly to address virtually all forms of shortcomings in the health sector. Ferraz has noted that while health rights litigation has increased over the years in Brazil, it is becoming clear that the main beneficiaries of these decisions are the middle class citizens and not necessarily the vulnerable and marginalised groups who often experience violations of their health rights.⁸⁷ He therefore, warns that there is need for vigilance so that the courts do not become pawns in the hands of the rich and middle class in society.

From the foregoing, a pertinent question that may arise from the *P.A.O* case will be: how will this case translate to meaningful results for hundreds of people living with HIV in Kenya? This is by no means an easy question to answer but it underscores the limitation of social rights litigation. Sometimes the much celebrated victory in court may mean little or nothing for the vulnerable and marginalised groups. This is because the government may either ignore or be slow in implementing the decision of the court. Thus, the poor and the marginalised may remain in the same situation they were before the decision of the court. In other words, access to essential services may remain a pipe dream for many in need of treatment. It should be noted that the court merely made a declaratory order that the provisions of the Anti-Counterfeit Act are inconsistent with the Kenyan Constitution but fails to specifically order the government to amend the provisions of the law. The Court merely said that 'it is incumbent on the state to consider' the provisions of the offending sections of the Anti-Counterfeit Act. This is a bit problematic and may create uncertainty as to what the government should do and the time frame for implementing this decision. Given the importance of life-saving medications for the existence of people living with HIV in the country, one would have expected a more definite and precise order from the court. It may be argued though, that the court is only being cautious so as not to encroach into the precincts of the executive or legislature. However, much as the court should not interfere with the work of other organs of government, it has the responsibility to ensure that these other organs do not act contrary to their constitutional obligations.

⁸⁶ S Gloppen & M.J. Roseman 'Introduction: Can Litigation Bring Justice to Health?' in S Gloppen & A Yamin (eds) *Litigating Health Rights: Can Court Bring more Justice Health?* (Harvard: Harvard Law School 2011) 7

⁸⁷ Ferraz O.M. 'Brazil-Health Inequalities, Rights and Courts: The Social Impact of Judicialisation of Health in in S Gloppen & A Yamin (eds) *Litigating Health Rights: Can Court Bring more Justice Health?* (Harvard: Harvard Law School 2011) 79-80; see also, V Gauri & D Brinks (eds) *Courting Social justice: Judicial Enforcement of Social and Economic Rights in Developing World* (Cambridge: Cambridge University Press 2008) 303.

It is interesting to note in the decision of *P.A.O* case the issue of non-discrimination was not conversed before the court. Given that the Anti-Counterfeit Act would mostly implicate access to generic medicine in the context of HIV/AIDS, one would have expected the petitioners to allege a violation of the provision of non-discrimination as contained in the Kenyan Constitution.⁸⁸ More importantly, the petitioners in this case are women living with HIV, which further reinforces the need to be sensitive to their situation. It is a known fact that in Africa HIV/AIDS bears a woman's face. The recent UNAIDS figure indicates that about 60 per cent of those living with HIV in Africa are women and that young women are three to four times more vulnerable to HIV than their male counterparts.⁸⁹ In addition studies have shown that due to their anatomy and other social cultural factors, women are more susceptible to HIV infection than their male counterparts. This situation necessitates a gender equality-based approach to realising the right to health. Aside from the historical disadvantage of women in many parts of the world, the HIV/AIDS pandemic has further exacerbated the inequality women face in many African societies.

The principles of equality and non-discrimination are well recognised under international human rights law. These include article 2 of both the ICESCR and ICCPR and articles 2 and 12 of CEDAW.⁹⁰ In its General Comment 20,⁹¹ the CESCR explained that the enjoyment of socio-economic rights guaranteed in the ICESCR must be without discrimination. In particular the CESCR notes that marginalised and vulnerable groups such as women, children, adolescents and people living with HIV must be given special attention in the enjoyment of socio-economic rights. In other words, any measure or steps taken by a state to realise socio-economic rights (particularly the right to health), must necessarily take into cognisance the situation and lived experiences of these groups.

In its earlier General Comment 14, the CESCR has noted that non-discrimination constitutes a minimum core of the enjoyment of the right to health which is not subject to progressive realisation.⁹² In the same vein, the CEDAW Committee in its General Comment 24⁹³ on women and health has explained that failure or reluctance on the part of the states to provide health care services specifically needed by women will constitute an act of discrimination contrary to the provision of the convention. In one of its concluding observations to the government of Kenya, the CEDAW committee has expressed grave concern that women and girls are particularly susceptible to HIV infection owing to gender specific norms.⁹⁴ The Committee further notes that the persistence of unequal power relations between women and men and inferior status of women and girls, may hamper their ability to negotiate for safe sex practices which may

⁸⁸ Article 27 of the Kenyan Constitution 2010.

⁸⁹ UNAIDS above note 12.

⁹⁰ CEDAW above note 25.

⁹¹ General Comment No. 20 of Committee on ESCR on Non-Discrimination in Economic, Social and Cultural Rights (article 2, para 2) E/C.12/GC/20.

⁹² ICESCR General Comment 14 above note 28.

⁹³ General Recommendation No 24 of CEDAW on Women and Health UN GAOR, 1999, Doc A/54/38 Rev 1.

⁹⁴ CEDAW Concluding Observations: Kenya 2011, (CEDAW/C/KEN/CO/7) para 39.

increase their vulnerability for infection.⁹⁵The Committee therefore urges the Kenyan government to adopt a gender sensitive approach in its HIV and AIDS prevention and treatment programme.

It should be noted that, the African Commission in *Legal Resources Centre v Zambia*,⁹⁶ has explained that the principles of equality and non-discrimination in articles 2 and 3 of the African Charter are very crucial and fundamental for the enjoyment of all other rights guaranteed in the African Charter. These statements attest to the fact that States cannot in anyway in the provision of health care services adopt a discriminatory approach, whether directly or indirectly .As shown in *P.A.O* case the fact that the Anti-Counterfeit Act may jeopardise access to life-saving medication for people living with HIV, maybe urged to constitute indirect discrimination by Kenya government against people living with HIV (particularly women living with HIV).

One other missing link in *P.A.O* is that there is little reference by the court to the jurisprudence of the African Commission in order to elucidate state obligation regarding the right to health. Throughout the judgement the court was willing to cite jurisprudence of the UN Human Rights system and did not make any reference to the jurisprudence of the African Commission. In recent times the African Commission has developed important jurisprudence and resolutions with regards to the right to health in general and access to medicine in particular. The decisions of the African Commission in both *SERAC*⁹⁷case and *Purohit* ⁹⁸case, both clarify the nature of states obligations with regard to the right to health under the African Charter. More importantly, the resolution of the African Commission on access to medicine ⁹⁹and declaration on HIV and human rights¹⁰⁰ require African governments to adopt a rights-based approach to HIV and AIDS particularly access to medicine for those in need. The African Commission explained in it resolution what measure African government must take in order to realise access to life-saving saving medication for their citizens. Given that Kenya has ratified the African Charter, one would have expected the court to be also guided by the decisions and resolutions of the African Commission. Therefore, it may be concluded that failure to cite jurisprudence of the African Commission was a missed opportunity. ¹⁰¹

⁹⁵ Ibid.

⁹⁶ *Legal Resource Foundation v Zambia* (2001) AHRLP 84 (ACHPR 2001) para 63.

⁹⁷*Social and Economic Rights Action Centre (SERAC) and Another v Nigeria*. Communication No. 155/96, (2001) AHRLR 60 (ACHPR 2001).

⁹⁸ *Purohit v The Gambia* above note 35.

⁹⁹ African Commission on Human and Peoples' Rights, ACHPR/Res.141 (XXXXIII)08: Resolution on Access to Health and needed Medicines in Africa.

¹⁰⁰ Resolution on the HIV/AIDS Pandemic –Threat against Human Rights and Humanity adopted at the 29th Ordinary Session of the African Commission held in Tripoli, Libya ACHPR Res.53/(XXIX)01.

¹⁰¹ According to article 2 of the Kenya Constitution, the Constitution is the “supreme law of the Republic . . .” and the “general rules of international law shall form part of the law of Kenya.” As such, it is our argument that the court should have referred to the jurisprudence of the African Commission in its judgement as part of international law.

6 CONCLUSION

The decision *P.A.O* is no doubt a significant development with regard to ascertaining state obligation as regard access to medicine. This is one of the few cases in Africa where a court has been called upon to determine the nature of the state's obligation with regard to intellectual property rights and the right to health. This decision attempted to clarify the duty of a state with regard to ensuring lifesaving medication for its citizens and protecting patent rights enjoyed by pharmaceutical companies. The judge in this case adopted a progressive; albeit rights-based approach in balancing state obligation with regard to human rights and intellectual property rights. The reasoning of the court in this case is a significant victory for people living with HIV and others who are in need of life- saving medication in Kenya and Africa as a whole.

The fact that the court found the Kenyan government in violation of the rights to life, dignity and health of its citizens due to the enactment of the Anti-Counterfeit Act emphasises the threefold obligation of states to respect, protect and fulfil all human rights particularly the right to health. While the case is no doubt a positive development in advancing the right to health, the fact that the court failed to make a specific order as to when the government should amend the offending provisions of the Anti-Counterfeit Act, consider the jurisprudence of the African Commission and the principle of non-discrimination raised by the case can be regarded as some of its shortcomings.

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