

## Anti-counterfeiting and access to generic medicines in Kenya

Reviewing *Patricia Osero Ochieng & 2 Others v Attorney General (2012)*

Jacinta Nyachae and Paul Ogendi

*On April 20, 2012, the Kenyan High Court delivered a ground-breaking decision that will, inter alia, enhance national, regional and international efforts aimed at improving access to affordable and essential medicines, including generics for people living with HIV. Indeed, the Patricia Ochieng case has been described as 'precedent-setting' and a 'trail-blazer' by both activists and academicians insofar as access to generic medicines is concerned in the context of anti-counterfeiting legislations.*

The decision by the Kenyan government not to appeal the court's ruling means that the judgment is legally binding, particularly with regard to the state's obligations to ensure access to medicines in line with the rights to life, health and human dignity guaranteed in the Bill of Rights of the Kenyan Constitution of 2010.

### A brief history of the case

Kenya enacted the Anti-Counterfeit Act No.13 of 2008 to combat counterfeit trade. The Act came into effect in 2009 and also established the Kenyan Anti-Counterfeiting Agency, which came into operation in 2010. The Act, which is aimed at deterring the illegal trade, established what constitutes counterfeiting offences and lists their penalties.

Interestingly, the petitioners in this case made it clear that they support the fight against counterfeiting in Kenya. However, they argued, sections 2, 32 and 34 of the Act were of concern. Their main concern was the ambiguity in the definition of 'counterfeiting' under section 2. In their opinion, it provides sufficient room for abuse by both overzealous intellectual property rights owners and enforcement officers, exercising their statutory powers, to restrict access to essential and affordable medicines including generics. Similarly, section 32, which creates counterfeit offences, potentially criminalises generic manufacturing and importation. Section 34 on the powers of the Kenya Revenue Authority (KRA) Commissioner could also be exploited to seize and detain generics.

On July 8, 2009, three petitioners living positively with HIV approached the court to challenge the above controversial provisions. According to their petition, sections 2, 32 and 34 of the Anti-Counterfeit Act if implemented were

likely to infringe on their constitutional rights. The original petition was later amended to conform to the provisions of the new Constitution of Kenya enacted in 27 August 2010, which expanded the list of justiciable rights to include economic, social and cultural (ESC) rights, such as the right to health that buttressed the petitioners' case. These ESC rights include the right to life, to dignity and to health in terms of Articles 26(1), 28 and 43(1) of the 2010 Constitution. The petitioners' core argument in this regard was that access to essential medicines formed part of these rights, which, if restricted, would amount to a constitutional breach. They urged the court to protect their rights from this breach using evidence collected nationally and internationally.

The petitioners were later joined in their petition by the AIDS Law Project (ALP) as interested party and Mr. Anand Grover, the UN Special Rapporteur on the Right to the Highest Attainable Standard of Physical and Mental Health (the Special Rapporteur), as *amicus curiae*. The arguments of the interested party and *amicus curiae* served to support and further strengthen the position taken by the petitioners by emphasising the legal interpretation and adduction of relevant data before the court.

On April 2010, Justice Wendoh granted temporary orders to suspend the application of sections 2, 32 and 34 of the Anti-Counterfeit Act with regard to generic medicines. A final judgment was delivered by the High Court Judge, Justice Mumbi Ngugi, in 2012.

### The petition

In their petition, Patricia Asero Ochieng, Maurine Atieno and Joseph Munyi sought the following prayers:

- A declaration that the fundamental right to life, human dignity and health as protected and envisaged by Article 26(1), 28 and 43 of the Kenyan Constitution encompasses access to affordable and essential drugs and medicines.
- A declaration that, insofar as the Anti-Counterfeit Act severely limits access to affordable and essential drugs and medicines for HIV and AIDS, it infringes on petitioners right to life, human dignity and health guaranteed under Articles 26(1), 28 and 43.
- A declaration that enforcement of the Anti-Counterfeit Act insofar as it affects access to affordable and essential drugs and medications, particularly generic drugs, is a breach of the petitioners' right to life, human dignity and health guaranteed under the Kenyan Constitution.

## Violations of the right to health cannot be justified on the basis of intellectual property rights protection

In simple terms, the petitioners were essentially asking for three things: first, they wanted the Judge to declare access to medicines as being part and parcel of the constitutional right to health, human dignity and life. Second, they wanted the Judge to declare the provisions of the Anti-Counterfeit Act unconstitutional insofar as they limit access to essential drugs. Finally, they wanted the Judge to declare as unconstitutional the enforcement of the legislation in a manner that will affect access.

All these prayers were granted by the Judge as follows:

- The fundamental right to life, human dignity and health as protected and envisaged by Articles 26(1), 28 and 43(1) of the Constitution encompasses access to affordable and essential drugs and medicines including generic drugs and medicines.
- Insofar as the Anti-Counterfeit Act severely limits or threatens to limit access to affordable and essential drugs and medicines for HIV and AIDS, it infringes on the petitioners' right to life, human dignity and health guaranteed under Articles 26(1), 28 and 43(1) of the Constitution.
- Enforcement of the Anti-Counterfeit Act insofar as it affects access to affordable and essential drugs and medication, particularly generic drugs, is a breach of the petitioners' right to life, human dignity and health guaranteed under the Constitution.

### Petitioners' arguments

To begin with, the three petitioners were persons living with HIV and were dependent on generic medications. Therefore, their arguments were based on real-life experiences devoid of academic theory or legal jargon. Their main argument was that access to generic ARVs had 'normalised' their lives and therefore if access was restricted in any way they would die of opportunistic infections and/or develop resistance to the drugs they were taking. Either way, the results were undesirable for the government under national and international laws.

On the other hand, the interested party, ALP, relied heavily on the provisions of the new Constitution of 2010 in submitting its arguments. The crux of ALP's argument was that the relevant legislation in its current form infringed on the right to life (Article 26(1)), the right to dignity (Article 28) and the right to health (Article 43(1)) for persons living with HIV and AIDS. In addition, the ALP also argued that the legislation could potentially violate Article 45(1) of the

Constitution on the protection of family life. This was innovative since the HIV and AIDS scourge has been a major cause of havoc in family life, with many households in Kenya headed by eldest children and/or grandmothers. On the rights of the child, the ALP noted that Article 53(2) of the Constitution guaranteed the right to basic health-care services. They argued that the government relies heavily on generic medicines for its public health programmes because they are more affordable than branded medicines.

The *amicus curiae*, the Special Rapporteur, argued that access to needed medicines is an essential element of the right to health protected under international instruments ratified by Kenya. In his submissions, he reiterated that the definition of counterfeiting under section 2 'would certainly encompass generic medicines produced in Kenya and elsewhere'.

The biggest challenge thus remains the confusion between generic drugs and the violation of intellectual property rights. Access to generic drugs is likely to be affected on the pretext of protecting intellectual property rights. Due to the high pricing of branded medicines, the poor will be discriminated in accessing essential medicines. This will lead to a violation of the right to health which cannot be justified on the basis of intellectual property rights protection.

### Respondent's argument

The respondent's arguments on behalf of the state are summarised below.

- Generic medicine is not synonymous with counterfeit drugs; section 2 of the Anti-Counterfeit Act targeted only the latter.
- The definition of counterfeiting is 'clear and specific' and not ambiguous and therefore, contrary to the allegations proffered by the petitioners, it cannot be confused with generic medicines.
- The proviso contained under section 2 effectively safeguards generic importation under the Industrial Property Act and as such no derogation is likely to result from the implementation of the provisions of the anti-counterfeiting legislations.
- The legislation is meant to protect consumers from harm resulting from the use of counterfeit products, including the right to life.

In addition, the respondent dismissed the fear of possible seizures of generic drugs as witnessed in other jurisdictions, in particular, Netherlands, arguing that the legal regimes were different. For example, Kenya has the constitutional right to health and provisions of the Industrial Property Act on parallel importation.

### Issues for determination

In summary, the dispute before the court was whether, by enacting section 2 in its present form, and by providing the enforcement provisions in sections 32 and 34 of the Anti-Counterfeit Act, the State was in violation of its duty to

ensure conditions are in place under which its citizens can lead a healthy life; and whether these provisions will deny the petitioners access to essential medicines and thereby violate their rights to life, dignity and health under Articles 26(1), 28 and 43(1) respectively as well as sections 53 on access to basic health care for children.

### The judgment

In her judgment, the learned Judge relied on the minimum core argument and the limitation analysis provided for under Article 24 of the new Constitution to reach her decision. The fact that international law is part of Kenyan law under Article 2 of the 2010 Constitution proved very significant in accommodating international law jurisprudence and arguments from the UN Special Rapporteur that tilted the balance in favour of the petitioners.

With regard to the limitation analysis, any limitation of a right must be 'reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom'. Secondly, the judge must consider the following:

- the nature of the right or fundamental freedom;
- the importance of the purpose of the limitation;
- the nature and extent of the limitation;
- the need to ensure that the enjoyment of rights and fundamental freedoms by any individual does not prejudice the rights and fundamental freedoms of others; and
- the relation between the limitation and its purpose and whether there are less restrictive means to achieve the purpose.

### Parting shot

The Judge in her parting shot singled out section 2 of the Anti-Counterfeit Act for amendments to conform with the government's obligations under the constitutional rights to life, health and human dignity concerning access to generic medicines, particularly with regard to chronic diseases such as HIV and AIDS that affect the majority poor who are unable to afford branded medicines.

### The meaning of the judgment to the HIV and AIDS actors

In order to demonstrate the actual meaning of the judgment for HIV and AIDS actors, it is important to examine the events after the judgment. First, in the Court about 40 people wore T-shirts branded with slogans such as 'health is my right', 'access to generic medicines' and 'fight counterfeits not generics'. These messages would seem to have been clearly considered by the judge in her judgment. This was evident by the fact that all persons present in court, including persons living with HIV and AIDS, burst into protracted singing and dancing outside the court afterwards, signaling victory.

Second, the case attracted national, foreign and international media attention. The importance of this case for HIV and AIDS actors therefore cannot be overemphasised.

Third, the decision effectively settles the debate con-

cerning the supremacy of human rights over intellectual property rights protection and by extension, over any other interest. Human rights therefore actually trump private interests including commercial interest.

Finally, the decision effectively underscores the crucial role played by generic medicines in intervening in public health emergencies and particularly the fight against HIV and AIDS. At the end of 2011, about 1.6 million people in Kenya were living with HIV. An estimated 743 000 Kenyans are eligible for antiretroviral treatment, of whom 539 000 currently receive it. Kenya's national HIV treatment programme relies heavily on access to generic antiretroviral medicines. By the middle of 2001, triple combination therapy was available from Indian generic manufacturers for as little as US\$ 295 per person per year.

The price of antiretrovirals for low- and middle-income countries has continued to fall. Between 2004 and 2008, first-line antiretroviral regimens in lower- and middle-income countries declined by 30–68%. The most widely used drug combination is available for US\$ 64 per person per year. In Kenya, all government programmes offer first-line antiretrovirals free of charge.

Moving forward, appropriate policies should be put in place to further develop the sector to combat public health scourges in the country for the benefit of everyone.

### The legal import of the judgment

Legally speaking, this judgment means that sections 2, 32 and 34 of the Kenya Anti-Counterfeit Act have been declared unconstitutional and therefore cannot be enforced insofar as they affect access to affordable and essential medicines. The judgment also affirms that protection of human rights ranks higher than other obligations of the government, including the protection of private intellectual property rights. It is therefore crucial that all legislations conform to the important legal principle that the case has established. Failure to conform means that the courts will not be hesitant to declare such legislation unconstitutional, as happened in this case.

### Lessons learnt

The following are the lessons learnt in this case.

- In terms of strategy, the decision has positively confirmed the effectiveness of public interest litigation as a tool for advocacy. The mobilisation of people living with HIV also proved significant. The decision by the court provides an authoritative and persuasive tool for use by various actors, even beyond the HIV and AIDS sector, to promote access to medicines locally and internationally.
- There is need to ensure that a country's constitution and legislation are safeguarded against infringements that may be motivated by ulterior motives. While the right to life and dignity were present in the previous Constitution, in the writer's opinion the quality of the decision that led the government not to appeal against it was informed by the fact that the new Constitution expressly protected the right to health. Further, it al-

lowed for the application of international law including foreign decisions in the domestic context.

- The synergy of all actors including ALP and the Special Rapporteur was effective. The participation of other organisations in terms of mobilisation of persons living with HIV and AIDS and others was crucial in proving the existence of a category of persons who rely on generic medicines. This issue therefore was readily accepted by the court. Finally, wide media coverage ensured that the decision achieved the publicity that it deserves to influence access to medicines campaigns.

### Way forward

While the judgment marked a great victory for actors in the HIV and AIDS sector, care should be taken to avoid complacency. In particular, the civil society organisations involved in working around access to medicines should:

- engage the government in amending the anti-counterfeiting legislation to protect access to generic medicines in Kenya;
- review other existing laws on intellectual property, medicines and laws related to the right to health with a view to advocate for amendments to further guarantee access to generic medicines in line with the new Constitution; and
- engage in the discourse of medicines regulation to guarantee the quality, efficacy and safety of medicines in Kenya.

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