



## Patricia Asero Ochieng, et al. v. Attorney General, et al.

Petition 409 of 2009

**Country:** Kenya

**Region:** Africa

**Year:** 2012

**Court:** High Court at Nairobi

**Health Topics:** Child and adolescent health, HIV/AIDS, Medicines, Poverty

**Human Rights:** Right to health, Right to life

### Facts

The Petitioners were citizens of Kenya living with HIV. They claimed that provisions of the Anti-Counterfeiting Act, 2008 (the Act) severely restricted access to affordable, essential medicines, including generic medicines for HIV-related diseases, in violation of their fundamental rights to life, dignity and health protected under articles 26(1), 28 and 43 of the Constitution of Kenya.

The Petitioners and others unable to afford branded medicines began receiving regular supplies of medicines for HIV-related diseases free of charge following the passage of the Industrial Property Act in 2001, which allowed for the importation of affordable, generic drugs into the country. The HIV and AIDS Prevention and Control Act, 2006 established the Government's obligation to ensure the availability of resources to guarantee access to medicines to treat HIV. The Petitioners submitted that 90 percent of people living with HIV in Kenya used generic medicines imported by the Government or donors.

The Petitioners argued that the Government failed to specifically exempt generic medicines from the definition of "counterfeiting" in section 2 of the Act. They argued that the definition of counterfeit goods in the Act was unclear and could be interpreted to include generic medicines. This would effectively prohibit the importation of generic medicines into Kenya and allow generic medicines to be seized at any time by authorities. This in turn would severely reduce access to affordable, life-saving medicines, including for HIV-related diseases.

The Petitioners further contended that the Government failed to consider how the Act would affect the rights and obligations accrued under the HIV and AIDS Prevention and Control Act, 2006 and the application of the Industrial Property Act.

The Petitioners also claimed that the definition of "counterfeit" in the Act went beyond the internationally accepted meaning of the term, as established in article 51 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization, which limits the use of the term to counterfeit trademark goods.

The Petitioners also noted that generic HIV medicines in transit to developing countries had in fact already been seized in the Netherlands and Germany pursuant to laws similar to the Act.

The Court also considered arguments submitted in an amicus brief from the United Nations Special Rapporteur on the Right to Health. The Special Rapporteur contended that the definition of counterfeiting in the Act effectively conflated generic medicines with medicines produced in violation of private intellectual property rights. He asserted that this would have a "serious adverse impact on the availability, affordability and accessibility of low-cost, high-quality medicines."

Respondent Attorney General argued that the term "generic drugs" was not synonymous with "counterfeit drugs." It was the Government's responsibility to protect people from the latter, which may lead to harm or even death. Respondent contended that the definition of counterfeit in the Act was sufficiently precise and did not encompass generic medicines. She argued that the Act provided "sufficient safeguards for users of antiretroviral drugs against those who market counterfeit goods but also ensures that they access antiretroviral drugs."

### Decision and Reasoning

The Court first noted the socio-economic context in which the petition arose. It held that there "can be no dispute that HIV AIDS constitutes a serious threat to the health and life of the petitioners," as well as the general public, particularly women and children. It noted that HIV continued to be a major challenge to Kenya's socio-economic development.

The Court stated that the availability of affordable antiretroviral drugs in Kenya under the Industrial Property Act had greatly enhanced the life and health of people living with HIV. The Court stated that the Act should be considered within this context.

The Court declared that the rights to life, dignity and health are "inextricably bound" and that without health, the right to life would be in jeopardy. It held that if a law had the effect of limiting the accessibility and availability of HIV medicines, it would "ipso facto threaten the lives and health" of people living with HIV "in violation of rights under the Constitution."

The Court examined the scope of the right to health under the Constitution in light of the right to health in international agreements, including article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), article 12 of the Convention on the Elimination of All Forms of Discrimination against Women, and article 24(1) of the Convention on the Rights of the Child. The Court noted that General Comment 14 of the Committee on Economic, Social and Cultural Rights, which interprets and elaborates the right to health in ICESCR, states that "the right to health embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life." The Court interpreted this to mean that the State must ensure people have access to the medicines they require to be healthy. The Court also noted that the right to access medicine has been recognized as an essential component of the right to health in other jurisdictions, including South Africa.

The Court held:

"The state's obligation with regard to the right to health therefore encompasses not only the positive duty to ensure that its citizens have access to health care services and medication but must also encompass the negative duty not to do anything that would in any way affect access to such health care services and essential medicines. Any legislation that would render the cost of essential drugs unaffordable to citizens would thus be in violation of the state's obligations under the Constitution."

The Court examined the definition of "counterfeiting" in section 2 of the Act and compared it with the World Health Organization's (WHO) definitions of counterfeit medicines and generic medicines. It noted the overlap between the definition of "counterfeit" in the Act and the WHO's definition of generic medicine and concluded that section 2 of the Act was "likely to be read as including generic medication." The Court declared that the danger that generic medicines could be seized under the Act was thus "manifest."

Finally, the Court noted that the tenor and object of the Act was to protect intellectual property rights, as evinced by the authority granted to the Commissioner appointed under section 13(1) of the Kenya Revenue Authority Act to "seize suspected goods upon the complaint of a patent holder." The Court found that the Act's purpose was not to safeguard consumers from counterfeit medicine. Had this been the Act's intention, it would have placed greater emphasis on standards and quality of medicines.

The Court held that sections 2, 32 and 34 of the Act threatened to violate the rights to life, dignity and health and must be reconsidered in light of the Government's constitutional obligation to protect the fundamental right to health, which encompasses access to affordable medicines, including generic medicines. The Court declared: "There can be no room for ambiguity where the right to health and life of the petitioners and the many other Kenyans who are affected by HIV/AIDS are at stake."

## Decision Excerpts

"The state's obligation with regard to the right to health therefore encompasses not only the positive duty to ensure that its citizens have access to health care services and medication but must also encompass the negative duty not to do anything that would in any way affect access to such health care services and essential medicines. Any legislation that would render the cost of essential drugs unaffordable to citizens would thus be in violation of the state's obligations under the Constitution." Para. 66.

"In my view, the definition of "counterfeit" in section 2 of the Act is likely to be read as including generic medication. I would therefore agree with the Amicus that the definition "would encompass generic medicines produced in Kenya and elsewhere and thus is likely to adversely affect the manufacture, sale, and distribution

of generic equivalents of patented drugs. This would affect the availability of the generic drugs and thus pose a real threat to the petitioners' right to life, dignity and health under the Constitution." Para. 78

"However, the right to life, dignity and health of people like the petitioners who are infected with the HIV virus 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. The primary concern of the respondent should be the interests of the petitioners and others infected with HIV/AIDS to whom it owes the duty to ensure access to appropriate health care and essential medicines. 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. There can be no room for ambiguity where the right to health and life of the petitioners and the many other Kenyans who are affected by HIV/AIDS are at stake." Para. 84.

"While such intellectual property rights should be protected, where there is the likelihood, as in this case, that their protection will put in jeopardy fundamental rights such as the right to life of others, I take the view that they must give way to the fundamental rights of citizens in the position of the petitioners." Para. 86

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