REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT NAIROBI

PETITION NO. 409 OF 2009

PATRICIA ASERO OCHIENG..... 1ST PETITIONER
MAURINE ATIENO ..... 2ND PETITIONER
JOSEPH MUNYI..... 3RD PETITIONER

AND

THE ATTORNEY GENERAL..... RESPONDENT

AIDS LAW PROJECT..... INTERESTED PARTY

JUDGMENT

Introduction

1. This petition raises critical issues pertaining to the constitutional right of citizens to the highest attainable standard of health. The petitioners are all citizens of Kenya who describe themselves as living positively with HIV/AIDS. They are apprehensive that their rights under the Constitution are threatened by the enactment of the Anti-Counterfeit Act, 2008, specifically sections 2, 32 and 34 thereof. They see these provisions as affecting or likely to affect their access to affordable and essential drugs and medicines including generic drugs and medicines thereby infringing their fundamental right

to **life**, **human dignity** and **health** as protected by Articles **26(1), 28** and **43** of the Constitution of Kenya.

2. By their Amended Petition dated 3rd November 2010, the petitioners seek the following prayers:-

    (a) A declaration that the fundamental right to life, human dignity and health as protected and envisaged by Articles 26(1), 28 and 43 of the Constitution encompasses access to affordable and essential drugs and medicines including generic drugs and medicines.

    (b) A declaration that in so far as the Anti Counterfeit Act, 2008 severely limits access to affordable and essential drugs and medicines including generic medicines for HIV and AIDS, it infringes on petitioners right to life, human dignity and health guaranteed under Articles 26(1), 28 and 43 of the Constitution.

    (c) A declaration that enforcement of the Anti Counterfeit Act, 2008 in so far as it affects access to affordable and essential drugs and medication particularly generic drugs is a breach of the petitioner's right to life, human dignity and health guaranteed under the Constitution.

(d) Any further orders, directions, declarations and remedies as this honourable court may deem fit and just in the circumstances.

3. The petition is supported by the affidavits of the petitioners, **Patricia Asero Ochieng, Maurine Atieno** and **Joseph Munyi** sworn on the 8th of July, 2009. The petitioners also rely on the affidavit sworn by **Joseph Munyi** on 16th September 2009 in support of their application of the same date seeking conservatory orders with regard to the implementation of the **Anti-Counterfeit Act**.

4. On 8th March 2010, the Aids Law Project, a non-governmental organisation registered in Kenya, was joined as an Interested Party to the proceedings. It filed an Answer in Support of the Amended Petition dated 16th November 2010 which was supported by the affidavit of **Jacinta Moraa Nyachae** sworn on 16th November 2010.

5. In the application dated the 16th of September 2009 which was supported by the Interested Party, the petitioners sought and

were granted on the 23rd of April 2010 conservatory orders staying the application of sections 2, 32, and 34 of the Anti-Counterfeit Act, Act No. 13 of 2008 (hereafter referred to as the Act), as relates to the importation of generic drugs and medication. The court also granted orders restraining the Anti-Counterfeit Agency from enforcing sections 2, 32 and 34 of the Act in relation to importation of generic drugs and medication pending the hearing and determination of this petition.

6. On the 17th of January, 2011, **Mr. Anand Grover,** the **United Nations Special Rapporteur for Health**, pursuant to orders made by Musinga, J, was joined as an Interested Party. The submissions filed in this matter by the Special Rapporteur dated 15th February 2011 appear to have been intended for **High Court Petition No. 97 of 2010 Aids Law Project -v-The Attorney General & Another** in which the Special Rapporteur appears as an Amicus Curiae. The Court notes, however, that this petition's number has been inserted and that they are therefore intended to form part of the pleadings in this case. No objection was raised with regard to the submissions.

7. The respondents oppose the petition and filed Grounds of Opposition dated 8th March 2010 in opposition to both the petition and the application for conservatory orders. The respondents also filed a replying affidavit sworn on the 4th of May 2010 by **Allan George Njogu Kamau,** the Chairman of the Board of the Anti-Counterfeit Agency, which had been joined in the petition as the 2nd respondent.

8. The petitioners filed written submissions dated the 28th day of February 2011. The Attorney General filed an outline of his submissions dated 21st July 2010 and written submissions dated 9th February 2012. The parties highlighted their submissions on the matter before me on the 24th of January 2012.

The Petitioners' Case

9. The petitioners are adults who have been living with HIV for periods ranging between 8 and 19 years. They have been taking HIV drugs for the last ten years or so since generic anti-retroviral (ARV) HIV drugs became widely available following the enactment of the **Industrial Property Act, 2001**. They take

1st line ARVs consisting mainly of 3TC, AZT and NVP, two tablets per day as prescribed.

10. The 1st petitioner depones that she gets her medication free of charge from *Medicins Sans Frontieres* (MSF) which runs a programme in conjunction with the government of Kenya to provide cheap and free access to medicines. The 2nd petitioner, who is also infected with HIV but is not currently on HIV drugs, has a 5 year old son infected since birth and who is on the 1st line anti-retroviral medication 3TC, AZT and NVD. He, too, receives his medication free of charge through a project funded by the government of Kenya and MSF. Like the other petitioners, she is unemployed and would not be in a position to afford any of the HIV/AIDS medication if she was required to purchase the drugs for her son. The 3rd petitioner, who has been living with HIV/Aids for 8 years, is also unemployed and receives his medication free of charge through a government programme. He started receiving a regular supply after the passage of the Industrial Property Act in 2001 which allowed the entry into the country of generic drugs.

11. The petitioners are apprehensive that the application and enforcement of the Act may deny them the right to enjoy the highest attainable standard of health as the cost of the HIV medication may substantially increase if they are denied an opportunity to purchase generic drugs.

12. In his submissions on behalf of the petitioners, Mr. Luseno stated that the petitioners are users of generic drugs which are taken daily, and this daily usage guarantees them the right to life without which no one can enjoy any other right in the Constitution. In recognition of the special status of persons affected and living with HIV and AIDS, the government enacted the **HIV and AIDS Prevention and Control Act, 2006** whose object was to extend to persons affected by HIV full protection of their human rights and civil liberties. This required that the government ensures availability of resources to ensure access to HIV drugs.

13. According to the petitioners, the Anti-Counterfeit Act poses serious danger to the rights of persons living with HIV Aids. They state as follows in the Amended Petition:

> **Para 10:** ***The Petitioners aver that the enforcement and application of the Act particularly sections 2, 32 and 34 will endanger their well being as they will be arbitrarily denied access to affordable and essential drugs and medication necessary for the fulfilment of the necessary quality of life, human dignity and health guaranteed under Articles 26(1), 28 and 43 of the Constitution.***

14. They state that the government has failed to acknowledge and specifically exempt generic drugs and medicines from the definition of counterfeit goods in the Act; it has failed to provide a clear definition of counterfeit goods under section 2 of the Act by defining counterfeit goods in the section in such a manner as would allow generic drugs to be included in the said definition thereby effectively prohibiting importation and manufacture of generic drugs and medicines in Kenya; it has also failed to take into account the provisions of the **HIV and AIDS Prevention and Control Act, 2006** in so far as the

petitioners have accrued rights under the said Act and have acquired a legitimate expectation that those rights will be protected; it has failed to clarify the application of the Industrial Property Act, 2001 in so far as the Act allows for exceptions necessary to make generic drugs available in Kenya; it has imposed an undue and unnecessary burden on the consumers of generic drugs and medicines of proving that generic drugs and medicines are not counterfeit goods as defined by the Act.

15. The petitioners submit that if the Act is applied and enforced, their right to life, human dignity and health as guaranteed under Articles 26(1), 28 and 43 of the Constitution is likely to be infringed. The availability and access to generic drugs will be severely restricted; such generic drugs and medication will be deemed counterfeit goods within the meaning of the Act and therefore liable to seizure at any time; and the cost of treatment for the petitioners will be likely to increase as they will be forced to rely on more expensive branded drugs. This, in turn, will result in fewer people having access to the essentials drugs for treatment of HIV and AIDS.

16. The petitioners submit further that the application and enforcement of the Act is in breach of the State's undertaking under the HIV and AIDS Prevention and Control Act, 2006 in which it undertook to take steps necessary, to the maximum of its available resources, to ensure access to healthcare services including access to essential medicines at affordable prices by persons with HIV or AIDS and those exposed to the risk of HIV infection. The enforcement of the Act is likely to intentionally deprive the petitioners of their right to life, human dignity and health in contravention of Articles 26(1), 28 and 43 of the Constitution.

17. Mr. Luseno submitted that the Act gives a very limited definition of what constitutes counterfeit goods. It fails to recognise positive steps taken by the state in enacting the HIV and AIDS Prevention and Control Act and exclude generic drugs from the application of section 2 of the Act. He referred to the replying affidavit of the Attorney General and contended that the petitioners were at the mercy of the Attorney General, police, and holders of intellectual property

rights with regard to the interpretation of what counterfeit goods are. He asked the court to be guided by the submissions of the Special Rapporteur on the mischief likely to result from the enforcement of section 2 of the Anti-Counterfeit Act.

18. The petitioners also argue that Section 2 of the Act subjects Kenyans to laws of other countries, as it accords owners of intellectual property rights in other countries the right to enforce those rights in Kenya without regard or compliance with Kenyan laws. The section, and indeed the entire Act, is in breach of international law to which Kenya was a party. Mr. Luseno submitted that **Article 51 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)** of the World Trade Organisation (WTO) limits the use of the term '**counterfeiting'** to counterfeit trademark goods; that the TRIPS Agreement forms part of Kenyan law in line with the provisions of Article 2 of the Constitution of Kenya; that the term 'counterfeit' as used in the Act goes beyond its internationally accepted legal meaning.

19. Mr. Luseno submitted with regard to Section 34 of the Act that it imports remedies which are exercisable by the police on

suspicion by an owner of intellectual property rights that there are counterfeit which have been imported. According to the petitioners, all the medicines they rely on are imported. Mr. Luseno submitted that 90% of persons with HIV use generic drugs imported by the government and donors. Should the police, on suspicion, detain the drugs at the port, the impact before a court is moved for an order to allow release of the goods to the market would be devastating. For petitioners who use the drugs daily, there may be loss of life by the time the suspicions are investigated. Section 2 seems to impose a burden on the user to satisfy the Commissioner that the drugs are not counterfeit and thus limits access to essential drugs and medication.

20. According to the petitioners, the State has a positive obligation under Article 24 of the Constitution on limitation of rights. It should take cognisance of human dignity and of the right sought to be limited, and under Article 24(2) (c), it should not limit the right so as to derogate from its core and essential content. The import of this with regard to the petitioners is that they can only enjoy their right to life if they have limitless

access to the generic drugs which they use daily, and any limitation to this access is in violation of Article 24(2) (c).

21. Mr. Luseno submitted that the state had conceded in the replying affidavit that there was a dispute as to the interpretation of section 2, but the state was asking the court to interpret the section in a manner that suits its interests. The state, according to Mr. Luseno, admitted that it did not intend to ruin the petitioners but it was failing to recognise its positive obligations under Article 21 and the HIV and AIDS Prevention and Control Act to ensure that the petitioners and persons with HIV are not faced with uncertainty about access to generic drugs.

22. The petitioners' position is that they are not opposed to the fight against counterfeiting, but they are a special class that was asking that legislation passed should not be contradictory of the state's positive obligations towards them. They referred to the incidents in other jurisdictions in which the application of provisions similar to section 2, 32 and 34 of the Act had led to seizure of generic drugs to the detriment of persons living

with HIV. The incidents in question were the seizure by customs authorities in the Netherlands of generic drugs for HIV destined for Brazil in December 2008 and the seizure in Germany of generic drugs manufactured in India which were bound for Vanuatu.

23. Mr. Luseno asked the court to take cognizance of the decision of Wendoh J who in granting conservatory orders in the matter had noted that ambiguity in the legislation is against the right to life; that suspicion in Section 34 will be used against access to the drugs, and that there has to be a better way of controlling counterfeit drugs. He argued that since the issuance of the conservatory orders, the government has been able to control counterfeiting without putting the petitioners at risk. He stated that the petitioners were asking government to consider the Act again and re-draft it as the lack of access to HIV drugs constitutes a real threat to life.

24. Mr. Luseno urged the court to be guided by international conventions in interpretation of the issue and referred the

court to the case of **Peter Waweru v. R Nairobi Misc. Civil Application No. 118 of 2004** (Unreported) where the court interpreted the right to life in the light of international treaties and concluded that this right encompassed the right to a healthy environment. He also urged the court to be guided by the decision of the Constitutional Court of South Africa in the case of **Fose –v- Minister of Safety and Security CCT 14/96** and **Minister of Health –v- Treatment Action Campaign and Others (1) 2002 (10) BCLR 1033 (CC)** and to fashion an appropriate remedy in accordance with the provisions of Section 23 of the Constitution.

25. On the respondent's submissions, Mr. Luseno pointed out that the state itself could not distinguish between counterfeit and generics and the respondent's counsel had used the word counterfeit in referring to generics consistently. He contended that if the government itself could not come out clearly as to what is counterfeit or generic, the risk that the Commissioner of Police would not be able to make the distinction was clear.

The Interested Party's Case

26. Mr Omwanza Ombati presented the case for the Interested Party in supporting the petition. He relied on the Answer In Support dated 16th November 2010 and the supporting affidavit of Jacinta Nyachae of the same date.

27. The position of the Interested Party, like that of the petitioners, is that the Act threatens the right to life, dignity and health of the petitioners and other persons infected with HIV. The Interested Party also takes the position that the Act violates the right to equality for persons with HIV.

28. With regard to the right to life, the Interested Party submitted that HIV is a life-threatening virus and that anti retroviral therapy is the most effective intervention for the survival of persons infected with the virus. When taken regularly as prescribed, such therapy is associated with a 90% reduction in deaths caused by AIDS.

29. The Interested Party contended that the denial of access to affordable medicines as the implementation of the Act

threatens, would lead to unnecessary pain and suffering that undermines the dignity and quality of life of people living with HIV and AIDS; that this would be a violation of their right to dignity as provided under Article 28 of the Constitution; that the Act has the potential to violate the right to family life as provided for under Article 45(1) of the Constitution yet family life is an inherent part of human dignity as normal family life is removed from people whose illness leaves them debilitated and unable to care for themselves.

30. On the right to equality, the Interested Party submitted that this right includes the full and equal enjoyment of all rights and freedoms, including equal rights to dignity, life and access to health care services based on Articles 27 and 43 of the Constitution.

31. The Interested Party argued also that the Act poses a threat to the rights of children. Article 53(2) of the Constitution guarantees to every child the right to basic health care services. Further, the state and everyone else is enjoined to

have the best interests of the child as the primary consideration in all matters involving children.

32. Like the petitioners, the Interested Party impugns Section 2 of the Act where it refers to protection of patents in Kenya or elsewhere. Mr. Ombati submitted that the nature of patent law is that it does not have international application, but the Act opens the door for anyone with a patent to come and have it protected in Kenya.

Submissions by the Amicus

33. The Special Rapporteur, **Mr. Anand Grover**, states that he filed his submissions in this matter in fulfilment of his mandate as outlined in Human Rights Council Resolution 6/29. He states that the resolution obliges the Special Rapporteur to make recommendations on issues surrounding the Right to Health, particularly in relation to laws, policies and practices that may represent obstacles to the right being realised. Mr. Ombati highlighted the Special Rapporteur's submissions.

34. According to the Special Rapporteur, while the objective of the Act is to prohibit trade in counterfeit goods, it is likely, as

currently written, to endanger the constitutional right to health guaranteed under Article 43 and in turn the right to life under Article 26 of the Constitution. This is so because the definition of counterfeit drugs in section 2 of the Act includes the ***"manufacture, production…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."*** In his view, this definition would certainly 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. It does not include an exception for medications, and does not 'avert' to the existence of generic drugs.

35. The Special Rapporteur submits that the definition of 'counterfeiting' within the Act effectively conflates generic medicines with medicines which are produced in violations of private intellectual property rights, and this conflation of legitimately produced generic medicines with those that

possibly violate intellectual property rights is likely to have a serious adverse impact on the availability, affordability and accessibility of low-cost, high-quality medicines.

36. This would lead to a situation in which medicines that are approved by regulatory authorities as being safe and effective are seized on the grounds that they are “counterfeit”; generic medicines destined for importation to Kenya being seized due to the uncertainty surrounding possible infringement of the Act upon delivery; significant delays of shipments of imported generic drugs at ports of entry to Kenya for inspection or legal clarification purposes; seizure of medicines at Kenyan ports by customs officials and police officers who are not specially trained to recognise the difference between counterfeit and generic products and an increase in the price of ARVs within Kenya which would make them expensive and financially inaccessible to those who need them.

37. The resulting limited access by patients to generic, medication will be a violation of their right to health as guaranteed by the Constitution and international treaties. Such violation, he

submits, cannot be justified on the basis of international obligations concerning intellectual property law or otherwise.

The Respondent's Case

38. Ms. Kimaiyo for the respondents, in opposing the petition submitted that the government cares for people with HIV/AIDS and has put in place mechanisms for their care and passed the HIV and AIDS Prevention and Control Act 2006. She relied on the submissions dated 9th January 2012 and the affidavit of **Allan George Njogu Kamau,** the Chairman of the Board of the Anti-Counterfeit Agency and argued that the term 'generic drugs' is not synonymous with 'counterfeit drugs'.

39. According to the respondents, the duties of the state under Article 43 are to ensure that its people attain the highest standard of healthcare. It is also the duty of the state to ensure that they enjoy the right to life. This is why the state enacted the Anti-Counterfeit Act as allowing counterfeit drugs will lead to death, and the Act was intended to protect citizens. The Act does not intend to bar generic drugs but seeks to

prohibit trade in counterfeits in Kenya. She submits that the term 'counterfeit medicines' is given the same definition in the Act as it is given by the World Health Organisation. She referred the court to the World Health Organisation definition of counterfeit drugs at page 43 and of generic drugs at page 45 of the publication attached to the Interested Party's Answer In Support of the Petition titled ***"Globalisation and access to drugs: Implications of the WTO/TRIPS Agreement*** and submitted that the definition of generics is not the same as that of counterfeits.

40. The respondents contend therefore that the definition of counterfeit as relates to medicine is very clear and specific and does not create the kind of ambiguity that gives rise to the petitioners' fears. The Act has given priority and special consideration to medicine because of its importance to both the state and the public. The petitioners' fears are therefore unfounded.

41. To the petitioners' submission that the Act should expressly provide for exemption of generic drugs from the definition of

counterfeits, the respondents argue that this is to demand too much as the Industrial Property Act did not provide just for importation of generic drugs but for other essential goods. It would not therefore make sense to name each and every limitation when such limitation could be captured in a proviso. The respondents referred to the proviso to section 2 which states that nothing in the provision shall derogate from the existing provisions under the Industrial Property Act and submitted that in the event of a conflict in interpretation, the provisions of the Industrial Property Act shall prevail.

42. According to the respondents, the intention behind the Anti-Counterfeit Act was to protect the public from the harm of using counterfeit goods and that extra care needs to be taken to ensure that the medicine in the market meets the required standard. Ms. Kimaiyo pointed out that for persons using anti-retroviral drugs, the risk posed by counterfeits is even greater. She therefore submitted that the Act should operate as intended in order to protect the rights of the petitioners as well as the general public.

43. With regard to the issue of whether or not the provisions in question are in breach of the constitutional rights of the petitioners, the respondents submitted that interpretation of the provisions of the Anti-Counterfeit Act does not and will not lead to violation of rights. The intention of the Act was to protect the lives of Kenyans from those few individuals who would deal with counterfeit goods, including drugs, for profit. For the court to grant the declarations sought would lead to breach, not protection, of the petitioners' fundamental rights. The Anti-Counterfeit Act provides sufficient safeguards for users of anti-retroviral drugs against those who market counterfeit goods but also ensures that they access anti-retroviral drugs. The petition is therefore an abuse of the court process which ought to be dismissed.

The Socio-Economic Context

44. In considering the issues that arise in this petition, it is important to bear in mind the socio-economic context in which they arise.

45. There can be no dispute that HIV AIDS constitutes a serious threat to the health and life of the petitioners in particular but to others within the general public who may be infected by the virus. This is particularly so with regard to children and women. The Interested Party has pointed out at Paragraph 27 of its Answer in Support of the Petition that

> ***'Approximately 110,000 children are born with HIV as a result of mother to child transmission of HIV. Scientists have accumulated significant research-generated evidence to show that with appropriate and affordable treatment this could be cut by between 30 and 50%.'***

46. The state also recognises the challenges that HIV poses. In the **Kenya National Aids Strategic Plan 2004-2009** that was made within the same period that the Anti-Counterfeit Act was enacted and commenced operation, the state notes that HIV/AIDS continues to be a major challenge to the country's socio-economic development. It notes that since the first case was discovered in the country in 1984, over 1.5 million people have died due to AIDS-related illnesses. This has resulted in 1.8 million children left as orphans. The state notes, however, that a combination of factors, including antiretroviral therapy, have

led to a decrease in the incidence and the numbers of those dying from HIV AIDS.

47. In the **2010 Country Report to the United Nations General Assembly Special Session on HIV and AIDS,** the National Aids Control Council, citing the **Kenya AIDS Indicators Survey (2007)** states that the average HIV prevalence among the general population aged 15-49 stands at 7.4%. Women have a higher prevalence compared to men, with women standing at 8.4% against 5.4% percent for men. It estimates the number of people living with HIV at between 1.3 to 1.6 million.

48. The **Kenya National HIV and AIDS Estimates (2010)** puts the cumulative number of children infected by HIV at 184,052 by 2009. It notes that the state has therefore put in place mechanisms to prevent mother to child transmission, with the Country Report indicating that in 2009, about 58,591 HIV positive pregnant women received antiretroviral prophylaxis to reduce the risk of mother-to-child transmission of HIV.

49. The Country Report estimates that more than 2.4 million children are orphans, half of them due to HIV and AIDS. Many of these orphans are in households that are targeted to receive government support in order to have improved access to nutrition, education and health. This underlines more than anything else the low economic circumstances in which many of those infected with HIV live.

50. In light of the above statistics, it is not hard to see the socio-economic implications of HIV/AIDS. It is now commonly acknowledged that without medical intervention and treatment, a person infected with HIV ultimately succumbs to the opportunistic infections that occur as a result of the compromised immune system. Many of those who are infected with the virus are, like the petitioners, unemployed and therefore financially incapable of procuring for themselves the anti-retroviral branded medication that they need to remain healthy. They are therefore dependent on generic anti-retroviral medication which is much cheaper and therefore more accessible to them.

51. From the pleadings and submissions before me, it is common ground that until the passage of the **Industrial Property Act in 2001 (Act No. 3 of 2001)**, it was not possible for poor people infected with HIV/AIDS to access anti-retroviral medication as the only ones available were expensive branded medicine. Generic anti-retroviral drugs were not available in Kenya as the existing legislation did not allow parallel importation of generic drugs and medicines. **Section 58 (2)** of the **Industrial Property Act, 2001** as read with **Rule 37 of the Industrial Property Regulations, 2002,** allowed the parallel importation of generic drugs. It is on the basis of this legislation that availability and access to anti-retroviral drugs has increased and greatly enhanced the life and health of persons such as the petitioners who have been living with HIV/AIDS.

52. It is against this context that any legislative measure that would affect accessibility and availability of anti-retroviral medicines must be viewed. If such measure would have the effect of limiting access, then such measure would ipso facto threaten the lives and health of the petitioners and others

infected with HIV and Aids, and would be in violation of their rights under the Constitution.

53. I take this view because, from the pleadings and submissions before me, while the petitioners, Interested Party and the Amicus on one hand and the respondents on the other have taken diametrically opposed positions on this petition, they are in agreement that the petitioners have certain rights which are guaranteed under the Constitution and by international law. The petitioners, as citizens of Kenya, have the right to life guaranteed under Article 26(1); they have the right to human dignity provided for under Article 28; they also have the right to the highest attainable standard of health guaranteed under Article 43(1) of the Constitution.

54. I have also not heard the respondents to dispute the right of children such as the 2nd petitioner's son to the highest attainable standard of health provided for under Article 53(1))c) or to deny that the best interests of the child should be the primary consideration in all matters involving children.

55. The rights which the petitioners see as likely to be violated by the implementation of the Act are guaranteed under the Constitution of Kenya and under international law. The parties have referred the court to various decisions in which the High Court has applied international law and urged the court to be guided by those decisions. However, Article 2 of the Constitution now makes it clear that all international treaties to which Kenya is a party are now part of the laws of Kenya. I am therefore bound by the Constitution to have regard to these treaties.

56. In my view, the right to health, life and human dignity are inextricably bound. There can be no argument that without health, the right to life is in jeopardy, and where one has an illness that is as debilitating as HIV/AIDS is now generally recognised as being, one's inherent dignity as a human being with the sense of self worth and ability to take care of oneself is compromised. What may not be agreed upon by the parties is the meaning and implication of the right to health, and the nature and implication of the positive obligation that

recognition of this right in the Constitution and international treaties places on the state.

Meaning and Implication of the Right to Health

57. Article 43(1) of the Constitution of Kenya provides that

> ***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;***

58. Article 12(1) of the International Covenant on Economic, Social and Cultural Rights provides as follows:

> ***'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.'***

59. The Convention then sets out at Article 12(2) the steps that each state party should take to achieve the full realization of this right. Such steps include the

> ***'prevention, treatment and control (of) epidemic, endemic, occupational and other diseases'***
>
> and
>
> ***'The creation of conditions which would assure to all medical service and medical attention in the event of sickness.'***

60. The right to health has also been recognised specifically with respect to women in the **Convention on the Elimination of All Forms of Discrimination against Women (Article 12)** and with respect to children in the **Convention on the Rights of the Child (Article 24(1))**. The centrality of this right vis a vis other rights cannot therefore be disputed.

61. In **General Comment No. 14 on the Right to Health**, the Committee on Economic, Social and Cultural Rights notes that

> ***'Health is a fundamental human right indispensable for the exercise of other human rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conducive to living a life in dignity.'***

62. The Committee notes further that:

> ***'The reference in article 12, paragraph 1, of the Covenant to "the highest attainable standard of physical and mental health" is not confined to the right to health care. On the contrary, the drafting history and the express wording of article 12, paragraph 2, acknowledge that the right to health embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the***

> ***underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment.*** (Emphasis added)

63. The '***socio-economic factors that promote conditions in which people can lead a healthy life'*** imply, in my view, a situation in which people have access to the medication they require to remain healthy. If the state fails to put in place such conditions, then it has violated or is likely to violate the right to health of its citizens.

64. The Committee on Economic, Social and Cultural Rights notes further in ***General Comment No. 17 on the right of Everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author*****, UN doc. E/C.12/GC/17, 12 January, 2006,** para. 35 that:

> ***'States parties thus have a duty to prevent unreasonably high costs for access to essential medicines.'***

65. The right to access medicine has also been recognised as an essential component of the right to health in other jurisdictions. In South Africa, the Constitutional Court, in the case of **Minister of Health and Others -v- Treatment Action Campaign and Others (supra)** held that the failure of the state to ensure access to the drug Nevirapine to pregnant women to prevent mother to child transmission of HIV was a violation of the constitutional right to the highest attainable standard of health.

66. 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.

67. The crux of the dispute before this court is whether, by enacting sections 2 in its present form, and by providing the enforcement provisions in section 32 and 34 of the Anti-Counterfeit Act, the State is 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 under Articles 26(1), 28 and 43(1), as well as sections 53 with regard to the rights of children.

The Anti-Counterfeit Act, Act No. 13 of 2008

68. The Act was passed in 2008 and received Presidential assent on 24th of December 2008. The Act commenced on the 7th of July 2009 in terms of Legal Notice No. 115. The Preamble to the Act states that it is an Act of Parliament intended to ***'prohibit trade in counterfeit goods, to establish the Anti-Counterfeit Agency, and for connected purposes.'***

69. The respondents have argued that the intention behind the Act was to prohibit trade in counterfeit goods, including

counterfeit medicines, which pose a danger to the life and health of Kenyans. The petitioners, while acknowledging the need to control trade in counterfeit goods, see the implementation of the Act in its present form as likely to lead to violation of their right to life, human dignity and health.

70. That there has been a problem with counterfeit goods entering the country and there is therefore a need to prohibit such trade is not in dispute. The right of holders of intellectual property rights to benefit from their innovations is also recognised, and the enactment of the Act may have been intended to be in fulfilment of Kenya's obligations under TRIPS to protect the rights of patent holders. The Amicus argues, however, that Kenya has fulfilled its obligations under TRIPS by enacting the **Industrial Property Act 2001**. This may indeed be the case as the Industrial Property Act provides for the rights of patent holders and civil remedies for the infringement of these rights. The Anti-Counterfeit Act appears to have been intended to bolster the protection of intellectual property rights by providing criminal sanctions for infringement.

71. The issue, however, is whether as the petitioners, the Interested Party and the Amicus allege, implementation of the Act will result in the violation of the constitutional rights of the petitioners as a result of the provisions of section 2 of the Act.

Section 2 of the Act

72. The petitioners impugn section 2 of the Act as likely to lead to an interpretation that includes generic drugs among counterfeit medicine and therefore lead to their criminalisation and seizure under Section 32 and 34 respectively. The Amicus argues that the Act conflates generic medicine with counterfeit medicine and is thus in agreement with the petitioners that the Act may lead to the seizure and thereby shortage of the generic drugs which are essential for the survival of the petitioners.

73. Section 2 provides as follows:

> ***"counterfeiting" means taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya or elsewhere in respect of protected goods-***

(a) the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;

(b) the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a 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) <u>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;</u>
(Emphasis added)

74. According to the respondents, this definition is the same as that used by the World Health Organisation (WHO). However, the WHO defines counterfeits in its Factsheet as '***Spurious/falsely-labelled/falsified/counterfeit***

medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source' and notes that such counterfeit drugs may be ***'compounded 'using the wrong ingredients, insufficient active ingredients, without active ingredients, or with fake packaging.'***

75. The danger that the petitioners see in the possibility of the terms **'generic'** and **counterfeit'** being used interchangeably is borne out by the fact that there have been instances, admittedly in other jurisdictions, in which generic medication has been seized while in transit on the basis that it is counterfeit. Such seizures have affected users of generic drugs in developing countries which, like Kenya, have large populations dependent on generic HIV medication for survival. The nature of international trade being the way it is, the risk of seizure of generic drugs bound for Kenya, whether at Kenyan ports or outside this country, cannot be ruled out.

76. Section 2 of the Act uses the words ***whether or not such products have correct ingredients, wrong ingredients, have***

sufficient active ingredients* or have fake packaging.'** As the Amicus points out, generic drugs ***'have the same composition and contain the same substances as patented formulations of the same drug, and are essentially identical copies, therefore can be used for the same purposes as their non-generic counterparts.'

77. The World Health Organisation defines generic medicine as ***"a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights".*** Generic drugs thus '....***have correct ingredients*... '** and *'**sufficient active ingredients**'* within the meaning of section 2 of the Anti-Counterfeit Act. In a legal regime that is focused on protection of intellectual property rights, the danger that such generic drugs can be seized under section 32 and 34 of the Act is therefore manifest.

78. 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. '***

79. The respondents argue that the intention of the Act is to safeguard the petitioners and others against the use of counterfeit medicines. A reading of the Act, however, shows a different intention. Section 32 provides as follows:

> ***It shall be an offence for any person to–***
>
> ***(a) have in his possession or control in the course of trade, any counterfeit goods;***
>
> ***(b) manufacture, produce or make in the course of trade, any counterfeit goods;***

(c) sell, hire out, barter or exchange, or offer or expose for sale, hiring out, barter or exchange any counterfeit goods;

(d) expose or exhibit for the purposes of trade any counterfeit goods;

(e) distribute counterfeit goods for purposes of trade or any other purpose;

(f) import into, transit through, tranship within or export from Kenya, except for private and domestic use of the importer or exporter as the case may be, any counterfeit goods;

(g) in any other manner, dispose of any counterfeit goods in the course of trade.

80. Section 33(1) of the Act provides that

'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.

81. At section 34(1) the Act provides that

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) imported into or enter Kenya during the period specified in the application:

82. Clearly, as the above provisions show, the tenor and object of the Act is to protect the intellectual property rights of individuals. This explains the rights granted to the intellectual property holder to complain about suspected violation of Intellectual property rights through trade in counterfeit goods, and the powers 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. Had the primary intention been to safeguard consumers from counterfeit medicine, then the Act should have laid greater emphasis on standards and quality.

83. The Anti-Counterfeit Act has, in my view, prioritised enforcement of intellectual property rights in dealing with the problem of counterfeit medicine. It has not taken an approach focused on quality and standards which would achieve what the respondents have submitted is the purpose behind the Act: the protection of the petitioners in particular and the general public from substandard medicine. Protection of consumers may have been a collateral issue in the minds of the drafters of the Act. This is why for instance, the rights of consumers of generic medicine are alluded to in the proviso to Section 2 of the Act.

84. 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.

85. Further, contrary to the respondents' counsel's assertion, the Anti-Counterfeit Act, being later in time, would prevail over the Industrial Property Act in the event of a conflict, and the proviso to Section 2 may not be of much help to the petitioners. Should the Act be implemented as it is, the danger that it poses to the right of the petitioners to access essential medicine which they require on a daily basis in order to sustain life is far greater and more critical than the protection of the intellectual property rights that the Act seeks to protect. The

right to life, dignity and health of the petitioners must take precedence over the intellectual property rights of patent holders.

86. 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. As the Committee on Economic Social and Cultural rights notes at Sparagraph 35 of General Comment No. 17.

> ***'Ultimately, intellectual property is a social product and has a social function. States parties thus have a duty to prevent unreasonably high costs for access to essential medicines, plant seeds or other means of food production, or for schoolbooks and learning materials, from undermining the rights of large segments of the population to health, food and education. Moreover, <u>States parties should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity, including the rights to life, health and privacy, e.g. by excluding inventions from patentability whenever their commercialization would jeopardize the full realization of these rights.</u>***

……States parties should also consider undertaking human rights impact assessments prior to the adoption and after a period of implementation of legislation for the protection of the moral and material interests resulting from one's scientific, literary or artistic productions.

87. In view of the matters set out above, I find that Sections 2, 32 and 34 of the Anti Counterfeit Act threaten to violate the right to life of the petitioners as protected by Article 26 (1), the right to human dignity guaranteed under Article 28 and the right to the highest attainable standard of health guaranteed under Article 43 (1) and grant the declarations sought as follows:

(a) 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.

(b) In so far as the Anti Counterfeit Act, 2008 severely limits or threatens to limit access to affordable and essential drugs and medicines including generic 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.

(c) Enforcement of the Anti Counterfeit Act, 2008 in so far 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.

88. It is incumbent on the state to reconsider the provisions of section 2 of the Anti-Counterfeit Act alongside its constitutional obligation to ensure that its citizens have access to the highest attainable standard of health and make appropriate amendments to ensure that the rights of petitioners and others dependent on generic medicines are not put in jeopardy.

89. I am grateful to the parties for their well-researched submissions and authorities.

90. This petition revolved around critical issues of great public interest and I therefore make no order as to costs.

Date at **Nairobi** this of 2012

Mumbi Ngugi

Judge