

Right to Health Encompasses Right to Access Essential Generic Medicines: Challenging the 2008 Anti-Counterfeit Act in Kenya

ALLAN MALECHE AND EMMA DAY

Abstract

To what extent has the right to access generic HIV medication been implemented in Kenya for the 1.6 million people living with HIV? How does this relate to the right to health under international and national law? This paper examines a constitutional challenge brought to the High Court of Kenya in 2009 (the “Anti-Counterfeit Case”) against the Anti-Counterfeit Act of 2008, which the petitioners, all of whom were living with HIV, argued would affect their ability to access affordable and generic antiretroviral medication. They argued that this would amount to a violation of their right to life, dignity, and health. This case is particularly interesting because the new Kenyan Constitution came into force in 2010, after the case had been filed, and specifically provided for the right to health for all of Kenya’s citizens, as well as giving direct effect to all international laws ratified by the Kenyan government. This paper follows the Anti-Counterfeit Case, which includes amendments filed by the petitioners following the new constitutional changes, the arguments by the different parties in the case, and the inappropriateness of counterfeit laws as measures to control substandard and falsified medicine. The case has resulted in the suspension of significant parts of the Anti-Counterfeit Act that would pose a challenge to parallel importation, and to the court issuing a directive that the sections be amended. The judgment is examined in detail, as are the broader implications of this case for other countries in Eastern Africa.

ALLAN MALECHE, LLB, is a Kenyan human rights lawyer and the Executive Director of KELIN, and is currently based in Kenya.

EMMA DAY, LL.M., is a British human rights lawyer and a Volunteer Lawyer at KELIN, and is currently based in Thailand.

Please address correspondence to Allan Maleche, Email: amaleche@kelinkenya.org and Emma Day, Email: dayemm@gmail.com.

Competing interests: None declared.

Copyright © 2014 Maleche and Day. This is an open access article distributed under the terms of Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/3.0/>), which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original author and source credited.

Background

PETITION 409/2009 (the “Anti-Counterfeit Case”), filed in the High Court of Kenya (“the court”) on July 8, 2009, speaks to the lives of three brave Kenyans who are living openly with HIV. Patricia Asero, Maurine Murenga, and Joseph Munyi are all adults who have been living with HIV for a period ranging from nine to 19 years. Asero has worked as a peer support counselor for MSF-Spain and is a member of the International Community of Women Living with HIV/AIDS. She has twice shared her testimony on issues of access to treatment at judicial dialogues in Johannesburg and Nairobi, in 2009 and 2013, respectively. Murenga recently founded Lean On Me, a community-based organization providing comprehensive care for adolescent girls living with HIV. She is also an HIV social worker based in Kisumu County, and an ambassador for the Here I Am campaign. She filed the petition on behalf of her son. Munyi is a member of the National Empowerment Network of People Living with HIV/AIDS and plays an active role in Kajiado Tumaini Support Group, a community-based group of people living with HIV.

Asero, Murenga, and Munyi have been on generic antiretroviral medications (ARVs) for the last eight years. They must adhere strictly to their treatment program, taking three tablets a day; if they fail to take the medications consistently—even for a few days—they risk becoming drug-resistant, which would then necessitate changing to a more expensive drug. The three take first-line ARVs, mainly 3TC (Lamivudine), AZT (Zidovudine), and NVP (Nevirapine), medicines which have been available in the Kenyan market since the passing of the Industrial Property Act 2001 (IPA). The IPA is defined as “an Act of Parliament to provide for the promotion of inventive and innovative activities, to facilitate the acquisition of technology through the granting and regulation of patents, utility models, technovations and industrial designs, to provide for the establishment, powers and functions of the Kenya Industrial Property Institute and for pur-

poses incidental thereto and connected therewith.”¹ The cost of treatment with these generic ARVs is approximately \$20 per month, an amount beyond the reach of any of the petitioners, particularly Murenga, whose son is on similar treatment.² The cost of treatment with non-generic medicines is beyond the reach of all but the wealthiest Kenyans.

The IPA was crucial in making such essential medicines available to large numbers of Kenyans because it allowed for parallel importation, which enables the importation of non-counterfeit drugs from other countries, without the permission of the intellectual property owner.³ Parallel importation can result in the availability of much cheaper pharmaceuticals in the local market. Parallel importation is defined as the importation of a good or service as to which exhaustion of an intellectual property right has occurred abroad. The goods and services subject to such trade are commonly referred to as parallel imports. “Parallel importation” as interpreted under Kenya’s Industrial Property Act differs slightly from the broader usage of “parallel importation” as defined above. Under Section 58(2) of the Kenya industrial Property Act as read with rule 37 of the Industrial Property Regulations 2002, it authorizes the importation of a generic version of an on-patent drug (e.g., importation of generic lamivudine manufactured by Cipla without the authorization of GlaxoSmithKline). This all changed in 2008, when Kenya’s Parliament passed the Anti-Counterfeit Act (Act No. 13 of 2008).⁴ This Act included essential medicines in the definition of “counterfeit” goods, making it an offense to sell or purchase such medicines, and allowing the intellectual property owner to ask the commissioner to seize and detain all suspected counterfeit goods.⁵ This presented a significant threat to parallel importation, and therefore to the availability of cheaper ARVs.

There was strong opposition from civil society as the Anti-Counterfeit Act went through parliament, and various civil society organizations (CSOs)

engaged in advocacy efforts with parliamentarians and other key government officials to point out the dangers in the Bill's provisions. The efforts were fruitless and the Act passed, eventually leading to the filing of the petition.

Access to essential medicines is recognized in UN General Comment 14 (2000) as an element of the right to health.⁶ However, there is a lack of consensus regarding which aspects of the implementation of this right are the responsibility of the State, and which aspects are the direct responsibility of pharmaceutical companies themselves. The 2008 Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines, and the UN Guiding Principles on Business and Human Rights arguably can be applied to pharmaceutical companies directly, as well as to States. This debate has been analyzed in depth by Moon in her article for a 2013 edition of this journal, "Respecting the right to access to medicines: Implications of the UN guiding principles on business and human rights for the pharmaceutical industry."⁷ This has implications for the extent to which States should regulate the importation of generic medicines, and for how broadly the term "counterfeit" should be defined in national law.⁸

Asero, Murenga, and Munyi argued that the Act would affect their ability to access affordable and essential medicines, including generic medicines. This, they argued, would infringe on their rights to life, dignity, and the highest attainable standard of health as outlined in Articles 26(1), 28, and 43(1) of the Constitution of Kenya 2010.⁹ The petitioners sought the following declarations:

1. 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;
2. that insofar 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 the petitioners' right to life, human dignity,

and health, guaranteed under Articles 26(1), 28, and 43 of the Constitution; and

3. 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 petitioners' right to life, human dignity, and health, guaranteed under the Constitution.

The attorney general was sued as the respondent, and the chairperson of the Anti-Counterfeit Agency was later enjoined. AIDS Law Project Kenya (ALP) and the United Nations Special Rapporteur for Health, Anand Grover, were enjoined as interested parties.¹⁰ Justice Roselyn Wendoh issued a temporary order on April 23, 2010 restraining the enforcement of the contentious sections as they relate to the importation of generic drugs and medication, pending the full hearing of the petition.¹¹ The petition was heard on January 24, 2012 and judgment delivered on April 20, 2012.¹²

The status of the right to health in Kenya

To understand the context of the Anti-Counterfeit Case and the importance of the Constitutional process, it is necessary to look at the opportunities provided by the Constitution of Kenya 2010. The promulgation of the Constitution of Kenya on August 27, 2010, was a milestone for the right to health. The 2010 Constitution contains a more expansive and progressive bill of rights and has made the right to health justiciable for all citizens at Article 43(1) and for all children at 53(1)c.¹³

The initial petition was filed in 2009, before the new Constitution came into force, and therefore the prayers for relief were much more limited. Under the old Constitution, people living with HIV had to link access to treatment and the right to health with the right to life, given the absence of an express provision on the right to health.¹⁴ Until August 2010, Kenya was a dualist state, whereby a treaty did not become law even after ratification—nor would the courts apply it—until and unless parliament passed an independent law importing the provisions of that treaty. Since August 2010, Article 2(6) of the

Constitution makes any ratified treaty or convention part of Kenyan law. Thus, once the government ratifies any treaty, it is law and courts can apply it without the need for legislation importing its provisions. This is the monist tradition. It should be noted, however, that even such treaty-based law is subject to Article 2(4) and is only applicable insofar as it does not contravene any provision of the Constitution.¹⁵ Thus, the provisions of ICESCR, the CRC, CEDAW, and the ACHPR, as they relate to the right to health, now form part of Kenyan law.¹⁶ The provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) are also now directly applicable in Kenya.

Furthermore, access to the courts under the Constitution of Kenya 2010 has been fundamentally enhanced under Articles 22(3) and 23(2) and (3). The articles reduce the privacy of *locus standi*, which was previously used as an excuse to dismiss human rights claims. This means that as well as people acting in their own interest, more applicants have standing to bring a claim, including anyone acting on behalf of another person, group, or in the public interest. The articles also require formalities to be kept to a bare minimum, and allow an avenue for concerned organizations, stakeholders, and people with certain expertise to appear as “friends of the court.”

Following these highly significant constitutional changes in 2010, the petitioners amended their pleadings to include arguments on the right to health and reliance on international instruments that Kenya had ratified that touched on the right to health and access to treatment. The amended petition was ground-breaking in advocating for the right to health in Kenya, and led other key stakeholders to enjoin as interested parties in the case. Their expert affidavits and submissions guided the court in making its decision.

Arguments advanced by the parties

To support their claim of the unconstitutionality of sections 2, 32, and 34, the petitioners and the friends of the court advanced three major arguments against the provisions of the Anti-Counterfeit Act. The first

argument was that the term “counterfeit,” as provided for in Section 2(d) of the Anti-Counterfeit Act, was too broad and vague, as it encompassed generic medicines produced in Kenya and elsewhere. The Act states that “counterfeiting” means taking certain actions without the authority of the owner of the intellectual property right subsisting in Kenya or elsewhere in respect of protected goods. “Counterfeit goods” means goods that are the result of counterfeiting by any means.¹⁷ This vague definition did not explicitly exclude medications and generic drugs, and did not recognize the positive steps that government had taken through the Industrial Property Act (2001) and the HIV & AIDS Prevention and Control Act (2006) to ensure access to generic medicines, including ARVs.¹⁸ The petitioners further argued that the definition in the Kenyan Act went beyond the requirements provided for under Article 51 of the TRIPS agreement, which limits the use of the term “counterfeiting” to trademarked goods.¹⁹ The definition of the term “anti-counterfeiting” has been debated extensively, with no clear consensus on the acceptable definition. In the Anti-Counterfeit Case, the court agreed with the petitioners’ arguments. A recent discussion paper from the UNDP entitled “Anti-Counterfeit Laws and Public Health: What to Look Out For” provides guiding principles to be taken into account when defining the term.²⁰ This issue has become extremely contentious, even within the WHO, where the term “spurious/falsely labelled/falsified/counterfeit” (SFFC) is used to capture all interpretations. As Clift explains in his detailed analysis of this debate for Chatham House, the term has a specific meaning in the field of intellectual property: a willful violation of trademark.²¹ The term is used more broadly in health to encompass medicines that have a falsified source or identity, but may not have breached any intellectual property laws. This includes substandard medicines, which may be in breach of quality control regulations but not necessarily in breach of any trademark rules.

The second key argument centered on the fact that the application of the three controversial sections of the Anti-Counterfeit Act would result in a violation of the rights to life, human dignity, and

health, as enshrined in the Constitution of Kenya 2010 and in international instruments ratified in line with Article 2(6) of the Constitution. The consequent inclusion of generic medicines in the definition of counterfeits would limit access to the lifelong generic ARVs used by the petitioners, since such generics could be seized within Kenya or in foreign ports. This, the petitioners argued, would severely limit their access to generic ARVs, without which they would not be able to enjoy the right to life, human dignity and health, or any other right enshrined in the Constitution of Kenya 2010. The Court agreed, observing:

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.

The third argument concerned the use of intellectual property rights laws to control sub-standard medicines. The petitioners argued that they were not opposed to the fight against counterfeit medicines, but to the use of intellectual property rights laws to deal with issues of substandard and falsified medicine. They cited the provisions of Sections 32 and 34 of the Anti-Counterfeit Act, which they argued were drafted in a manner that would safeguard the rights of individual intellectual property owners. They pointed out to the court that Section 34 gives powers to the police to impound goods considered to be counterfeit upon the suspicion of an owner of intellectual property rights anywhere in the world. They also cited incidences in the Netherlands where generic medicines suspected to be counterfeits were seized.²² The court, while agreeing with the arguments advanced by the petitioner, stated:

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. 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.

The practice of using anti-counterfeit laws to control standards of medicines was also addressed in the aforementioned UNDP paper, in which the authors concluded that the use of anti-counterfeit laws as a policy measure for curtailing the spread of substandard and falsified medicines is inappropriate. This observation and recommendation was shared by the findings of the Global Commission on HIV and the Law in their 2012 report *Risks, Rights and Health*.²³

The arguments advanced by the respondents, which the court found weak and non-persuasive, included: i) the definition of *counterfeits* at Section 2 was the same as the WHO definition, and given that neither refers to generic medicines, the definition was clear and specific, and would not give rise to any ambiguities; ii) there was no need to specifically exempt generic drugs from the definition of counterfeits, and doing so would amount to making excessive demands of the Anti-Counterfeit Act,

because the proviso at Section 2(d) was sufficient to exclude generic medicines; iii) the intention of the Anti-Counterfeit Act was to protect the public from the harm of using counterfeit goods, and extra measures needed to be taken into account to ensure that medicines in the market meet the required standard.²⁴ The risk for substandard drugs was much higher for those who were using ARVs and hence the need to protect their rights through the enactment of the anti-counterfeit law.

The court, in its findings, observed that the right to life, dignity, and health of the petitioner must take precedence over the rights of the patent holder.²⁵ The court further observed that even though intellectual property rights needed to be protected, where the enforcement of such rights would jeopardize the fundamental human rights of others, intellectual property rights should give way to the fundamental human rights. In doing so, the court made reference to the provisions of paragraph 35 of General Comment No. 3 of CESCR.²⁶ In its final decision, the court found that implementation of the three sections of the Anti-Counterfeit Act threatened to violate the right to life, dignity, and health of the three petitioners, and granted the declarations as sought. They further ordered the State to reconsider the provisions of Section 2 of the Act alongside the existing Constitutional obligations.

Conclusion

This landmark decision has since facilitated access to generic medicine for more than 430,000 people living with HIV in Kenya who are now in treatment.²⁷ The decision has also had implications beyond Kenya, particularly in Uganda, where civil society has used it to influence Uganda's parliament to order revision of the then-Anti-Counterfeit Bill 2010, which had provisions that would have affected access to generic medicines.²⁸ The new draft bill, which is approved by the cabinet and will soon be tabled for discussion in parliament, omitted the inclusion of generic medicines as counterfeits.²⁹

At the time of writing, an amendment bill to the Anti-Counterfeit Act has been tabled before the National Assembly.³⁰ The most relevant

amendment proposed is to Section 2 of the 2008 Act, which currently defines "counterfeiting" as "taking the [below enumerated] actions without the authority of the owner of intellectual property rights subsisting in Kenya *or elsewhere* in respect of protected goods..."[emphasis added]. One of the amendments proposes the deletion of the words "or elsewhere," which is a positive development because it will effectively stop Kenya from being required to police issues arising in other jurisdictions. However, the proposed amendment seems to have missed the opportunity to implement the judgment that challenged this legislation, and instead focuses largely on further strengthening of enforcement through introducing a board and a coordination/advisory committee. The real concern is that some amendments that Kenyan civil society organizations have been pushing for have not yet been achieved. These include limiting the scope of the definition of a counterfeit good to counterfeit trademarks and pirated copyright goods, as defined in Article 51 of TRIPS. The restriction of criminal liability on wilful trademark or copyright piracy on a commercial scale, as captured in Article 61 of the TRIPS agreement, is another element that has not been considered.³¹

At a regional level, the Draft East Africa Community Anti-Counterfeiting Bill and Policy, which are yet to be passed as of August 2014, contain broad provisions that define generic medicines as counterfeits.³² They also attempt to control the importation of substandard and falsified medicines using intellectual property law, in a similar way to the Kenyan Anti-Counterfeit Act. Efforts are still under way to ensure that these provisions are removed. The fact remains that anti-counterfeit laws are an inappropriate measure to control the spread of substandard and falsified medicines. Efforts should instead be placed on building the regulatory capacity of the Pharmacy and Poison Board, in the case of Kenya and other National Drug Authorities in East Africa, by ensuring they have sufficient human and financial resources. This will enable them to take the necessary expedited action against the proliferation of unsafe medicines and to set standards that must be adhered to by all stakeholders. Countries that

are still eligible to use TRIPS flexibilities should make maximum use of them, including using parallel importation and not granting pharmaceutical patents. Countries such as Kenya should ensure they do not enact laws that prescribe for more than TRIPS requires. The enactment and enforcement of consumer protection laws is an additional measure that can help control the spread of substandard and falsified medicines.

A recent case involving falsified ARVs in the supplies of Médecins Sans Frontières (MSF) in Kenya highlights the distinct difference between falsified and substandard medicines.³³ Falsified medicines may be fraudulently mislabelled, as was the case in the MSF batch of drugs in Kenya, and lack quality assurance as to their identity where the source has been fraudulently altered. In contrast, substandard medicines are legally registered, yet do not meet the prescribed standards set for them in law, meaning they could contain an incorrect dose, or could be contaminated by other ingredients. Cohn et al, in their analysis of the MSF incident, found that even though provisions in the 2008 Anti-Counterfeit Act were suspended at the time due to the court decisions described above, there were sufficient laws and regulations in Kenya to address the problems of falsified medicines, but in fact the greatest challenge in practice was in appropriate execution of these laws.³⁴ The authors also note that the danger of the 2008 Act was that its focus on intellectual property does not make a significant distinction between falsified medications and quality-assured generic medications.³⁵

The Kenyan decision in the Anti-Counterfeit Case demonstrates that strategic litigation can be used to ensure that access to the right to health is realized. In order to succeed in these kind of cases, it is important to have a clear case strategy from the outset, and to seek partnerships with people or organizations who possess relevant expertise to enjoin in the case, as this will help to ensure that the court has all the relevant decisions to make an informed judgment. We are of the view that this case will provide a pivotal reference point during deliberations on the development of laws and policies relating to anti-counterfeit goods at the East African regional

level, and at the national level of each member state in East Africa which intends to pass laws similar to the Kenyan one.

References

1. The Industrial Property Act, 2001 CAP. 509. Available at <http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=CAP.%20509>.
2. B. Larson et al., "ART treatment costs and retention in care in Kenya: A cohort study in three rural outpatient clinics," *Journal of the International AIDS Society Vol. 16* (2013), p. 18026. Available at <http://www.jiasociety.org/index.php/jias/article/view/18026/2788>.
3. Section 58(2) of the Industrial Property Act, 2001 as read with Rule 37 of the Industrial Property Regulations, 2002.
4. Anti-Counterfeit Act, 2008 CAP. 130A (An Act of Parliament to prohibit trade in counterfeit goods, to establish the Anti-Counterfeit Agency, and for connected purposes). Available at <http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=CAP.%20130A>.
5. Anti-Counterfeit Act 2008, CAP. 130A, Sections 32-3, Available at <http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=CAP.%20130A>; and see further http://www.haiafrica.org/index.php?option=com_content&view=article&id=87:anti-counterfeit-act-in-kenya-is-commenced-despite-human-rights-petition-filed-in-court&catid=93:latest-news4.
6. UN Committee on Economic, Cultural and Social Rights (CESCR), General Comment No.14: The Right to the Highest Attainable Standard of Health (Article 12) at Article 12 (a), and paragraphs 42 & 43 (2000) (E/C.12/2000/4). Available at <http://www.refworld.org/docid/4538838do.html>.
7. S. Moon, "Respecting the right to access to medicines: implications of the UN Guiding Principles on Business and Human Rights for the pharmaceutical industry" *Health and Human Rights: An International Journal* 15/1 (2013), pp. 33-43. Available at <http://www.hhrjournal.org/2013/10/03/respecting-the-right-to-access-to-medicines-implications-of-the-un-guiding-principles-on-business-and-human-rights-for-the-pharmaceutical-industry/>.
8. See further J. Lee & P. Hunt "Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines," *The Journal of Law, Medicine & Ethics* 2/40 (2012), pp. 220-233. Available at <http://www.ncbi.nlm.nih.gov/pubmed/22789042>.
9. Constitution of Kenya, 2010. Available at <http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=Const2010>.
10. The AIDS Law Project (ALP) is a non-governmental organization which works exclusively to promote equal

rights and justice for people living with HIV and AIDS. See <http://www.aidslawproject.org/about-aids-law-project/>; see also <http://www.ohchr.org/EN/Issues/Health/Pages/SRRightHealthIndex.aspx>, and <http://www.ohchr.org/EN/Issues/Health/Pages/SRBio.aspx>.

11. M. Suleiman, "Kenya: Court Victory Against 'Anti-Counterfeit' Agenda," *AllAfrica.com* (April 23, 2010). Available at <http://allafrica.com/stories/201004230734.html>.

12. Judgment: Petition No 409 of 2009. Available at <http://kelinkkenya.org/wp-content/uploads/2010/10/Judgment-Petition-No-409-of-2009-Anti-counterfeit-case.pdf>.

13. Constitution of Kenya 2010, Article 43(1) a: "Every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care." Available at <http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=Const2010>.

14. The Constitution of Kenya Revised Edition 2009 (2008). Available at <http://www.kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/ConstitutionofKenyaRepealed.pdf>.

15. Constitution of Kenya 2010 Article 2(4) reads: "Any law, including customary law that is inconsistent with this Constitution is void to the extent of the inconsistency, and any act or omission in contravention of this Constitution is invalid." Available at: <http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=Const2010>.

16. See the United Nations Treaty Collection for the full texts of ICESCR, CRC, CRPD, and CEDAW, available at: treaties.un.org; and see <http://www.achpr.org/instruments/achpr/> for the full text of the ACHPR.

17. Anti-Counterfeit Act 2008, CAP. 130A. Available at <http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=CAP.%20130A>.

18. HIV and AIDS Prevention and Control Act 2006, CAP. 246A. Available at <http://www.kenyalaw.org:8181/exist/kenyalex/actview.xql?actid=CAP.%20246A>.

19. World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 51. Available at http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_03_e.htm#article51.

20. UNDP Discussion Paper, "Anti-Counterfeit Laws and Public Health: What to look out for." Available at <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/discussion-paper---anti-counterfeit-laws-and-public-health---wha/>.

21. C. Clift, *Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward?* Chatham House Briefing Paper (UK: Centre on Global Health Security, 2010/01). Available at <http://www.chathamhouse.org/publications/papers/view/109517>.

22. P. Radheika, "UN agency protests Dutch Seizure of Indian HIV drugs," *LiveMint* (March 6, 2009). Available at <http://www.livemint.com/Companies/UfeintEsvQXoZn-hJy4pwwK/UN-agency-protests-Dutch-seizure-of-Indian>

HIV-drugs.html.

23. UNDP Global Commission on HIV & the Law, *Risks, Rights & Health* (New York: UNDP 2012). Available at <http://www.hivlawcommission.org/index.php/report>.

24. Provided that nothing in this paragraph shall derogate from the existing provisions under the Industrial Property Act, 2001 (No. 3 of 2001).

25. For the full judgment, see: kelinkkenya.org/wp-content/uploads/2010/10/Judgment-Petition-No-409-of-2009-Anti-counterfeit-case.pdf.

26. UN Economic & Social Council, *General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para. 1, of the Covenant)*, 14 December 1990, E/1991/23. Available at <http://www.refworld.org/docid/4538838e10.html>.

27. National AIDS & STI Control Programme (NAS-COP), Anti-Retroviral Therapy. Available at http://nascop.or.ke/anti_retroviral_therapy.php.

28. The Anti Counterfeiting Goods Bill 2010, Bill No. 22 (Uganda). Available at <https://www.dropbox.com/s/l8c3s-33rgmghrfe/The%20Anti%20Couterfieting%20Goods%20Bill%202010.pdf>; H. Zakumumpa, "Kenya: Court Ruling on Generic Dru8gs Sets Precedent for the Region," *AllAfrica.com* (May 4, 2012). Available at <http://allafrica.com/stories/201205050203.html>.

29. P. Jaramogi, "Cabinet Approves Anti-Counterfeit Bill," *New Vision* (March 18, 2013). Available at <http://www.newvision.co.ug/news/640745-cabinet-approves-anti-counterfeit-bill.html>.

30. Kenya Gazette Supplement No. 75 (National Assembly Bills No. 24) p. 2595 (May 30, 2014), Bill for Introduction into the National Assembly – The Statutes Law Miscellaneous (Amendments) Bill 2014. Available at http://kenyalaw.org/kl/fileadmin/pdfdownloads/bills/2014/TheStatuteLaw-Miscellaneous_Amendments_Bill2014.pdf.

31. A memorandum containing the proposed amendments by Civil Society Organizations is available at <http://kelinkkenya.org/wp-content/uploads/2010/10/Anti-Counterfeit-Act-to-Access-Generic-Medicines-in-Kenya-booklet.pdf>.

32. Health Action International (HAI) Africa, "A briefing paper on the utilization of trips flexibilities in the EAC region." Available at http://www.haiafrica.org/index.php?option=com_content&view=article&id=273:a-briefing-paper-on-the-utilization-of-trips-flexibilities-in-the-eac-region&catid=78:news.

33. J. Cohn et al, "When falsified medicines enter the supply chain: Description of an incident in Kenya and lessons learned for rapid response," *Journal of Public Health Policy* 34(1) (2013), pp. 22-30. Available at <http://www.ncbi.nlm.nih.gov/pubmed/23172047>.

34. *Ibid*, p. 27. These laws include the Food, Drugs, and Chemical Substances Act; the Penal Code; the Pharmacy and Poisons Act; the Trade Descriptions Act; and the Kenya Industrial Property Act.

35. Ibid, p. 29.