LEGISLATION AND USE OF TRIPS AGREEMENTS

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Kenya Legal and Ethical Issues Network on HIV & AIDS

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OUTLINE OF PRESENTATION

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NO ACCESS TO MEDICINES = DENIAL OF RIGHT TO HEALTH = DENIAL TO RIGHT TOLIFE = DEATH

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BACKGROUND

- More than 5 million people globally are now receiving HIV treatment
- Globally there are 10 million people living with HIV who are eligible for treatment under the new WHO guidelines are still in need

- In 2009, there were an estimated 2.6 million [2.3 million–2.8 million] people who became newly infected with HIV globally.

  – In sub-Saharan Africa, where the majority of new HIV infections continue to occur, an estimated 1.8 million [1.6 million–2.0 million] people became infected in 2009;

- An estimated 370 000 [230 000–510 000] children were newly infected with HIV in 2009 (a drop of 24% from five years earlier).
  – Source UNAIDS 2010 Global Report

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Background (Contd)

- The effects of antiretroviral therapy are especially evident in sub-Saharan A frica, where an estimated 320 000 (or 20%) fewer people died of AIDS-related causes in 2009 than in 2004.

- Investments in providing access to medicines, particularly antiretroviral (A RVs) are paying off in many countries across the world, including in the Eastern & Southern A frican Community.

- However these gains can only be tentative as the burden for treatment increases due to people on treatment living longer (the good news) but also due to continued high levels of new infections (the bad news).

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Background (Contd)

- For every person put on treatment, there are two new infections. (Michel Sidibe's message on World A IDs day 2009)

- HIV is both an emergency for those without treatment and a chronic condition for those with it.

- The targets for A ccess to HIV medicines are therefore still far despite the good progress made so far

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TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

- The Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organisation, signed in Marrakesh, Morocco on 15 April 1994.

- The TRIPs Agreement sets out minimum levels of standards concerning intellectual property in the form of copyrights, trademarks, patents industrial designs, geographical indicators, integrated circuits and trade secrets.

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The TRIPS Agreement

- In 2001, trade ministers adopted "the Doha Declaration" – a TRIPS A greement and Public Health policy which, among other things, declared that:

- the TRIPS A greement does not and should not prevent Members from taking measures to protect public health.

"we affirm that the A greement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and in particular, to promote access to medicines for all".

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The TRIPS Agreement (Cont'd)

TRIPS flexibilities enable WTO members to:

- Interpret the three criteria of patentability (novelty, inventive step, and industrial application);
- Issue compulsory licenses and government use orders;
- Make use of the international exhaustion of rights to parallel import;
- Apply a number of general exceptions available under Article 30 of TRIPS;
- To make use of transitional arrangements.
- The application of these flexibilities is what has seen the prices of medicines go down

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Cont'd…

- ARVs provide a perfect illustration of how patents allow manufacturers to keep the price of medicines high, and how competition brings those prices down.

- In Kenya for example, when parallel importation began through the use of the Industrial Property Act of 2001, the price of ARVs became as low as KSh 500 (about USD6) a month, down from KSh 6000 (about USD75) a month only a year

- In South Africa, the ARV regimens fell from over R3000 (about USD424) per month in the 1990s to less than R150 (about USD21) per month for the standard first line regimen used in the public sector today.

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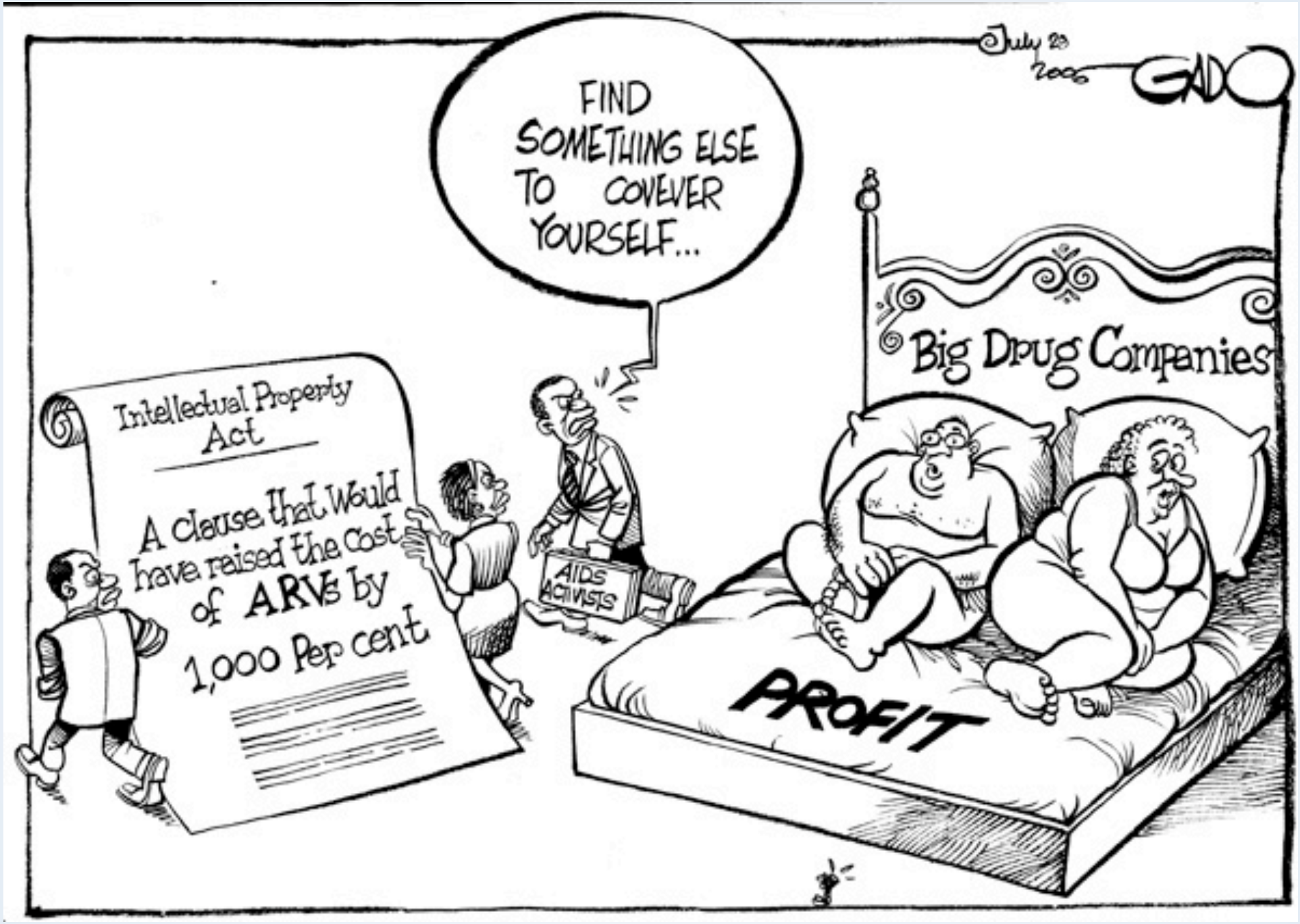
July 28 2006
GADO
FIND SOMETHING ELSE TO COVEVER YOURSELF...
Big Drug Companies
Intellectual Property Act
A clause that would have raised the cost of ARVs by 1,000 Per cent
Aids Activists
PROFIT

COUNTERFEIT LEGISLATION

- The Laws **IRRATIONALLY** seeks to enforce the intellectual property (IP) rights of manufacturers of goods and services with an aim of ensuring public health, safety and product quality concerns.

- By providing criminal and civil sanctions against those who infringe these rights.

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EAC COUNTRY POSITIONS

- Burundi (No law on counterfeiting)
- Kenya (A law exists that is already in-force, The Anti Counterfeit Act 2008)
- **Rwanda** (the only country in EAC to ever use paragraph 6 of the Doha Declaration, providing a temporary waiver to TRIPS rules to enable the importation of generic drugs from Canada)
- **Tanzania** (the 2008 Merchandise Marks Regulations in Tanzania)
- Uganda (A draft bill due to be presented in parliament- The Anti-Counterfeiting Goods Bill 2010)- *Negative clause on generic medicines has been amended to exclude generic medicines*.
- **Zanzibar** (Bill for an Act to set up a Zanzibar Bureau of Standards)

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REGIONAL POSITION

- East African Community Policy on Anti-Counterfeiting, Anti-Piracy and Other Intellectual Property Rights Violations" (hereinafter 'EAC Anti-Counterfeiting Policy')
  - Was discussed in Arusha on 6th December 2010

- The East African Community Anti-Counterfeit Bill, 2010

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WHY SHOULD WE BE CONCERNED ABOUT THESE LAWS AND POLICIES

- They will have a negative effect towards access to medicines especially generic medicines:
  - For example the Kenyan Law and the EAC Bill have an overbroad definition of counterfeit i.e. “substantially identical copies” which means that every generic medicine is a counterfeit since generic medicines are identical copies of originator products

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- The implications, in terms of access to HIV treatment:
  - notwithstanding the major efforts that have gone into improving access to medicines by governments, civil society, international organizations and agencies and the private sector
  - we are still very far from achieving universal access, such provisions in the law will only contribute towards hindering universal access.
- Questions are raised with regard to the impact on access to medicines, including:
  - the possible impact on efforts to enhance the local manufacture of medicines, vaccines and diagnostics
  - regional trade in generic medicines more generally

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- The EA policy and bill are aimed at improving the "business investment" climate in the region to favor certain industrial players

- Policy does not take into account the existing efforts to increase access to medicines

- Does not take into account national legal regimes that deal with health food standards

- Its approach and solutions suggested are not evidenced based and over look the basics of IP tenets

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DAILY NATION
Wednesday September 3, 2008

COUNTERFEITS

Proposed law on fake goods could turn out to be a killer, warn lobbyists

The rules may be used by big drugs firms to fight cheap imports for the poor

By ELLY WAMARI

"The moment you stop generics, you are inviting death!" The emotive statement cut across the breakfast table with a resounding impact. A loud silence followed.

As the next speaker took the floor, he did so with a determination to rub in the point even much deeper. "This Bill might end up killing people," declared Mr Patrick Mubangizi, the principal host of the August 28 forum organised by Health Action International (HAI) Africa to critique the Anti-Counterfeit Bill 2008, especially on matters concerning medicines.

Mr Mubangizi is the coordinator of HAI-Africa, a network of civil society organisations, healthcare providers, academia, and individuals whose principal agenda is to promote access to essential drugs. His statement mirrored what had been the hallmark of the discussion around the Bill — that it posed serious threats to public health.

Worrying levels

Teenagers take part in a walk to create Aids awareness. Lobby

icines to the detriment of public interest.

tions of counterfeiting and lays out round penalties without consideration of special circumstances under which patents could be exploited for the common good of the public.

"The anti-counterfeit Bill has various important strategies to combat generalised counterfeiting in Kenya, but it does not distinguish medicines from other goods, and opens avenues for interested parties to undermine access to more affordable generic medicines," concludes Mr Munyi.

Accordingly, its enactment in its present form may open up holes that would be used by multinational pharmaceuticals to stifle competition offered by generic versions. It needs to be amended, according to Mr Kamau, Mr Munyi and Mr Mubangizi.

Less costly

Mr Kamau, who is a consumer of antiretroviral drugs (ARVs), comes up again with another practical example. He is convinced that the Bill as it is, could be used by anti-generics pharmaceutical companies to reverse the gains realised soon after the enactment of the IP Act 2002, which allowed importation of less costly generic ARVs and caused prices to drop by about 90 per cent. More people have since been able to afford the drugs, including himself.

"When the IP Act 2001 came into force, entry of generics into the market increased and prices of ARVs and antibiotics dropped. Generics are priced at 20 to 80 per cent less than innovator brand equivalents," he says. "They are not counterfeits. They are medicines that work," he asserts.

EU & INDIA TRADE AGREEMENT

- India is one of the most renowned countries for the manufacture of good quality, more affordable generic medicines.

- India is able to manufacture and export generic medicines due to its flexible laws that allow for the market entry of generics prior to patent expiry. Developing countries are then able to purchase these lower cost medicines from India.

- The majority of people on AIDS treatment across Africa depend on Indian ARVs and other essential medicines. India has in fact been described as 'the pharmacy of the developing world' and its capacity to continue in this role is simply a matter of life and death for millions.

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EU & INDIA TRADE AGREEMENT

- An FTA is a trading agreement where tariffs are removed among members but maintained against the outside world

- The Free Trade Agreement (FTA) being negotiated between India and the EU threatens the availability of generic medicines due to the strict IP protection terms being proposed by the EU.

- These terms go beyond the minimum requirements imposed by the World Trade Organization (WTO) Trade-related Agreement on IP Rights (TRIPS)

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HOW THE FTA WILL AFFECT ACCESS TO ESSENTIAL MEDICINES

- It introduces the following negative provisions:
  - **Patent Extension**: At present, patents on medicines last for 20 years from the date of filing. The proposed extension in the EU- India FTA will be equal to the time elapsed between the filing of the application for a patent and the date of the first market authorization. Extending the monopoly period for a pharmaceutical patent holder limits access to essential medicines as it hinders competition and allows the maintenance of monopolistic (high) prices.

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- **Data Exclusivity**: This is the period of time in which a countries National Medicines Regulatory Authority is prohibited from available clinical data to register a generic medicine. This essentially extends the patent holder's monopoly, given that generic medicines are effectively barred from entering the market. This, of course, has significant cost and access implications

- **Enforcement chapter with border measures**: Whereas TRIPS obliges states to allow the IP rights-holder to lodge an application to customs authorities to suspend the release of imported counterfeit trademark into free circulation, the EU - India FTA enables the patent holder to block the importation, exportation, re-exportation, entry or exit of goods *suspected* of infringing *any* intellectual property rights in the customs territory. This further empowers IP rights-holder in a manner that would enable them to exploit their monopolistic practices and further undermine the generic industry

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- **EU – India FTA potentially limits the TRIPS flexibilities granted to ALL developing countries in TRIPS (and re-confirmed in the Doha Declaration)**

- Both the EU and India have committed to the Doha Declaration on TRIPS and Public Health, 2001 and the Global Strategy and Plan of Action on Intellectual Property, Innovation and Public Health (GSPA) adopted by the World Health Assembly in May 2008.

- The GSPA adopts the principle of placing public health over commercial interests; the Doha Declaration similarly affirms that the TRIPS Agreement does not bar member countries from taking measures to protect public health.

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NEED FOR MORE CONCERN

- **Lack of transparency in the negotiations**
  - Concerns have been raised over the fact that negotiations for the FTA have been behind closed doors.8 Draft texts have not been made public to marginalized communities, civil society groups, or public health advocates.
  - Such individuals or groups interested in the FTA have had to rely on leaked versions of the documents. This is inconsistent with principles of accountability, participation, and access to information.

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WHAT NEEDS TO BE DONE?

- These laws & policies should be challenged at the draft stage to ensure they don't erode the gains made with regards to access to treatment.

- Where the laws are already in force, one can consider legal action as is ongoing in the Kenyan scenario

- We must be vocal and protest about all FTA that are likely to erode gains made so far in accessing essential medicines

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THE KENYAN COURT CASE

- Three PLWHIV, filled a case in 2009 against the Government in relation to the law, to the effect that provisions that mark generics as counterfeits will affect their right to health, human dignity and life
- Court has issued stay orders preventing the law from applying to generic medicines
- Special Rappourteour on health has been allowed to enjoin on case
- Case comes up in April 2011

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CONCLUSION

- An intellectual property (IP) enforcement-based approach to public health and safety is unlikely to address any real health safety and product quality concerns **The safety of products, including products over which IP rights are conferred, can only be confirmed through quality testing and market surveillance and not through enforcement of IP Laws.**

- **India should not accept any terms in its FTA negotiations with the EU which will escalate the prices of ARVs and other essential medicines** and defeat India's long effort towards access to medicines. Less than half of the poorest and most marginalized people in the developing world can access the essential medicines they need for their health and life. Under half of those in need of treatment for HIV in Africa are receiving it.
- **It is simply not acceptable to further undermine peoples' struggles to realize their human right to life through initiatives such as the EU – India FTA**. The people who have looked to India's "pharmacy for the poor" are those who now call on India to resist: and to not sign this FTA.

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“The proposed India-EU FTA threatens the steady supply of generic drugs, and our ability to access new, innovative medicines. Without generics, the more than one million people currently receiving treatment in South Africa today, including myself, would not have access to ARVs. We rely on these medicines to keep us healthy and alive.”

- TAC General Secretary Vuyiseka Dubula

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ACKNOWLEDGEMENTS

- Christa Cepuch - HAI
- Commissioner Catherine Muyeka Mumma – CIC/KELIN
- Sisulue F. Musungu- HAI
- Moses Mulumba – HEPS - UGANDA
- Paula Akugizibwe – ARASA
- Emma Day- KELIN
- Melba Katindi – KELIN
- Vuyiseka Dubula - TAC
- To all Persons Living with HIV and on ARV treatment
- The three petitioners in HCC Petition N.o 409 of 2009 Nairobi. P.A.O and 2 others vs. The Attorney General of Kenya

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USEFUL LINKS & WEBSITES

- http://www.deccanchronicle.com/op-ed/unhealthy-effects-ftas-701
- http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf
- http://www.msf.ca/newsmedia/news/2010/04/eu-india-fta-last-chance-to-remove-provisions-that-block-access-to-medicines/
- http://www.ip-watch.org/weblog/2009/07/07/kenyan-aids-patients-seek-to-overturn-anti-counterfeiting-law-as-unconstitutional/.n
- www.kelinkenya.org
- www.haiafrica.org
- www.kenyalaw.org
- http://data.unaids.org/pub/SpeechEXD/2009/20091201_exd_wad_message_en.pdf.
- http://www.unaids.org/globalreport/documents/20101123_GlobalReport_full_en.pdf
- http://rwanda.e-regulations.org/show-list.asp?l=en&mid=46
- http://www.msf.ca/news-media/news/2010/04/eu-india-fta-last-chance-to-remove-provisions-that-block-access-to-medicines/
- http://www.luc.edu/law/activities/publications/ilrdocs/vol5_no2/vol5_no2/cotter_rwanda.pdf
- http://dailynews.co.tz/columnist/?n=16596&cat=columnist
- http://www.seatini.org/publications/factsheets/trips.htm

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EU WHY DO YOU WANT TO DENY THE RIGHT TO HEALTH & LIFE TO THE FUTURE KENYAN PRIME MINISTER?

THANK YOU FOR YOUR ATTENTION

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