Outcome Of The Technical Meeting

Held At Maanzoni Lodge In Machakos County
26 November 2013
Abbreviations

1. Background

2. Proceedings of the Technical Meeting
   2.1 Overview
   2.2 General Observations on the Act
   2.3 Specific reasons why the Anti-counterfeit Act presents a threat on access to medicines in Kenya
      i. Definition Problem
      ii. Criminal Liability
      iii. Power of seizure and storage
      iv. Goods in transit
      v. Rules of Evidence
      vi. Composition and operation of the Board

3. Way Forward

   Proposed amendment to the definition clause of the Anti-Counterfeit Act

APPENDIX I: List of Participants at the Technical meeting

AGENDA
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRIPS</td>
<td>Trade-Related Aspects of Intellectual Property Rights</td>
</tr>
<tr>
<td>TRADE</td>
<td>Related Aspects of Intellectual Property Rights</td>
</tr>
<tr>
<td>CSOs</td>
<td>Civil Society organizations</td>
</tr>
<tr>
<td>PLHIV</td>
<td>Persons Living with HIV</td>
</tr>
<tr>
<td>CIC</td>
<td>Commission on the Implementation of the Constitution</td>
</tr>
<tr>
<td>ALP</td>
<td>Aids Law Project</td>
</tr>
<tr>
<td>NEPHAK</td>
<td>Network of Persons Living with HIV and AIDS in Kenya</td>
</tr>
<tr>
<td>IP</td>
<td>Intellectual Property</td>
</tr>
<tr>
<td>INN</td>
<td>International Non-proprietary Name</td>
</tr>
</tbody>
</table>
A

ccess to more affordable medicines in the public health sector in Kenya and other developing countries plays a critical role in treating and managing opportunistic diseases from HIV, tuberculosis and malaria. However, access to affordable medicines is affected by several factors including intellectual property rights protection and enforcement via anti-counterfeit legislations as well as inadequate utilization of agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities regarding public health. What is more recent legal and tariff barriers imposed on pharmaceutical products also threaten access to treatment in the Kenyan health system.

The Anti-Counterfeit Act (the Act) was enacted in 2008 amidst strong opposition from health civil society organizations (CSOs) and People Living with HIV (PLHIV) in Kenya. The main concern was that the Act as enacted threatened access to generic pharmaceuticals in Kenya and the region. The Kenyan CSOs responded by filing a successful petition to challenge the constitutionality of Kenya’s Anti-Counterfeit Act of 2008 was filed in the High Court. The case of Patricia Asero Ochieng and 2 Others v. the Attorney General & Another Petition No. 409 of 2009 in the High Court of Kenya

The High Court ruled in favor of the petitioners and declared Sections 2, 32 and 34 of the Act unconstitutional. It also held that the definition of “counterfeit” in the Act confuses generics with counterfeits and was therefore likely to adversely affect the manufacture, sale and distribution of life saving generic drugs. This in turn would hamper the availability of the generic drugs and pose a threat to the petitioners’ right to life, dignity and health under the Constitution. The provisions of the Act are yet to be amended.

Kenya is in the process of implementing the Constitution of Kenya 2010. The Commission on the Implementation of the Constitution (CIC) recommended the review of the existing laws to ensure compliance with the provisions of the Constitution. The process of reviewing the Anti-Counterfeit Act thus provides a timely opportunity to address the problematic provisions that pose a threat to access to medicines in Kenya.
2.1 Overview

The technical meeting on the Kenya Anti-Counterfeit Act was convened by KELIN in partnership with the Aids Law Project (ALP) and the National Empowerment Network of Persons Living with HIV and AIDS in Kenya (NEPHAK). The meeting was held on the 26th of November, 2013 with the support of UNAIDS and UNDP. The technical meeting was aimed at developing a common understanding on anti-counterfeiting legislations and its impact on access to medicines. Such common understanding would inform the development of a consolidated CSOs position on the proposed amendments contained in the Kenyan law.

The technical meeting of nine participants brought together local advocates on intellectual property, access to medicines in Kenya, experts from Geneva (Third World Network) and New York (UNDP).

The preliminary sessions were aimed at contextualizing the IP agenda. Melba Katindi of KELIN presented the background that informed the need for the technical meeting to discuss the Act. This was followed by a presentation by Catherine Kirk of UNDP on the Global Counterfeiting Agenda which brought out the broad issues in legislation that would pose a threat on access to medicines. Sangeeta Shashikant of the Third World Network presented on Intellectual Property, Public Health and Counterfeiting. This expounded on the provisions contained in the TRIPs agreement and the various terminologies and language that was suitable to safeguard against TRIPs plus provisions in national legislations. A presentation by Paul Ogendi on the key legal concerns in the Kenya Anti-Counterfeit Act that needed amendment then led to a comprehensive discussion on specific provisions and the possible implications on access to medicines.

The one day workshop allowed technical discussions on the legislation in Kenya which resulted in:

i. The identification of potential threats that the Act has on access to medicines.
ii. A unanimous position on the appropriate scope and operation of the Act.
iii. A unanimous amendment on the proposed reviewed definition of counterfeiting.

These positions consequently led to the development of this document that highlights and makes recommendations on the key aspects to be addressed in reviewing and/or amending the Anti-Counterfeit Act.
2.2 General Observations on the Act

During the discussions the following general observations were made:

1. The need to distinguish between quality issues and counterfeiting as it is defined by the current Act. A clear understanding that counterfeiting legislations cannot sufficiently address and should not purport to address issues of quality.

2. Different IP categories require different aspects of protection. The Act combines the different IP categories into one term of counterfeiting. Whereas in practice they cannot be applied uniformly, and the TRIPs agreement treats them differently.

3. The need to ensure that all IP related initiatives are balanced giving due consideration to public and private interests implemented in a manner conducive for the social and economic welfare of Kenyans.

4. Intellectual property rights are private rights and thus it is mainly the responsibility of the IP holder to enforce such rights and not the government.

5. Major concerns that the Act may contain numerous provisions that are beyond what is required by the TRIPS Agreement (TRIPS-plus) that will hamper development and access to essential medicines including legitimate trade of items such as medicines, knowledge and technology.

The particular issues raised in this regard are as follows:

(i) The border measures proposed in the Act extended to all IPR violations and to goods imported, exported and in transit although Article 51 of the TRIPS Agreement only requires border measures for counterfeit trademark goods and copyright pirated goods that are imported.

(ii) The Act criminalizes all IPR violations although Article 61 of TRIPS only requires criminalization in cases of willful trademark counterfeiting or copyright piracy on a commercial scale.

6. Concerns that the Act will hamper access to affordable medical products and local production of generic medical products.

7. Confusion with the term “counterfeit”, which in the TRIPS Agreement means acts done willfully and on a commercial scale in relation to counterfeit trademark goods and pirated copyright goods. Quality and safety issues should be dealt with distinctly from issues pertaining to intellectual property rights.

8. Concerns about the expansive scope of the Act. Although counterfeiting is defined in the TRIPS Agreement as pertaining to trademark infringements, the Act extends its scope to include patents and other IPR violations.

9. It was observed that the Act was largely criminal and all components of counterfeiting comprised an offence without acknowledging other penalties already provided for in the Penal Code, Copyright Act and Trademarks Act.
2.3 Specific reasons why the Anti-counterfeit Act presents a threat on access to medicines in Kenya

i. Definition Problem

- It combines the different IP categories into one term of counterfeiting whereas the TRIPs agreement treats them differently; in particular:
  a) The confusion with regard to the different categories of IP and the use of one term “counterfeiting” with reference to each of them although each of these categories is distinct under the TRIPS Agreement;
  b) Extra territorial application of IP laws i.e. the definition makes an act “counterfeit” in Kenya although the act took place outside of Kenya;
  c) Terms such as “imitated in such manner and to such a degree that those other goods are identical to or substantially similar to protected goods” that is likely to deem all similar local products counterfeit.
  d) Claims of infringement cannot be investigated in the same manner for the different types of IP (a customs official will not be able to determine a patent infringement in the same way they may be able to identify a trademark infringement).

- Use of the term “identical or substantially similar” and “colorable imitation” is problematic in the case of medicines, where medicines are intentionally identical in composition and for clinical reasons often also in appearance. The term “confusingly similar” is also problematic for medicines, where the branding often intentionally derives from the international nonproprietary name (INN).

- The definition covers counterfeiting aspects in Kenya and elsewhere.
- Goes beyond TRIPs requirements by extending to patents and other IP regimes such as utility models.

Although the definition captures aspects of quality the Act in dealing with counterfeiting cannot address issues of quality.

Solution:
Limit the scope of the act to counterfeit trademarks and pirated copyright goods as defined in Art 51 of the TRIPs agreement.

ii. Criminal Liability

- The law goes beyond TRIPS provisions by using criminal provisions on civil private rights that should be enforced individually using civil procedures.
- The law enforces private rights using public funds.
- Fear of having a criminal claim of patent infringement brought may act as a disincentive to undertake research and development, or to import legitimate generics.

Solution:
Criminal liability should be limited to only on willful trademark or copyright piracy on a commercial scale as captured in Art 61 of the
iii. Power of seizure and storage

- The broad powers given to the authorities under Section 23 can be abused and result in unwarranted delays and deteriorated products.
- The powers in this section are against those outlined in the constitution.
- No timeframes in which the release of goods in case of resolved dispute e.g. for public health sensitive provisions should not be held for medicines not to be held for more than 10 days.

Solution:
Timelines and suitable storage facilities especially for medicines and guidelines for compensation in the event of unwarranted seizure.

iv. Goods in transit

- Provisions in the Act apply to goods not only imported but those exported as well as those in transit. This in essence implies that Kenya is utilizing its resources to enforce IP rights that are recognized in other jurisdictions (They may not necessarily violate rights in Kenya)

Solution:
- Reflect Art 60 of the TRIPs agreement which deals with De Minimis Imports (exempt small quantities of goods)
- Limit border measures only to goods imported into Kenya

v. Rules of Evidence

- The rules of evidence captured under Sec. 26 are unconstitutional whereby the defender is presumed guilty and the onus of proof is on them to prove otherwise.

Solution:
Rules of procedure should conform to the Constitution and the Evidence Act
Complainants should first establish their rights before alleging violation

vi. Composition and operation of the Board

- Section 6(1)(k) allows the Chief Executive of the Kenya Association of Manufacturers to be part of the Board. This raises serious concerns about conflicts of interest as the private sector clearly has strong commercial interests it wishes to protect and its involvement could conflict with the objectivity and independence of the Board. Section 7(d) raises concern as it makes the Board and the Agency ACA susceptible/vulnerable to allegations of corruption. The agency should only be funded by the government and should not be allowed to take any other contributions/gifts (e.g. from the private sector).

Solution:
- Delete s 6(1)9k)
- Delete S 7(d)
3. Way Forward

1. The recommendations, concerns and proposals made at the technical meeting:
   a) Shall inform the discussions of a larger meeting to assist civil society develop a consensus on the issues and develop an advocacy strategy.
   b) Once adopted at the larger CSOs meeting, will guide the development of specific proposals on proposed amendments to the Act.

2. Final proposals on specific amendments shall be developed by 15th December 2012:
   a) For submission to the Kenya Anti-Counterfeit Agency to be taken into account in the review of the Act.
   b) For submission to parliament to inform the process of amending the Act.

Proposed amendment to the definition clause of the Anti-Counterfeit Act
Counterfeiting refers to an act done willfully and on a commercial scale in relation to counterfeit trademark goods and pirated copyright goods

Counterfeit Trademark goods refer to:
(a) Goods including packaging, bearing without authorization a trademark which is identical to the trademark validly registered [in Kenya] in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in Kenya
Pirated copyright goods refer to:
(b) Goods which are copies made without the consent of the right holder or persons duly authorized by the right holder in Kenya and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right in Kenya.

Counterfeiting and Counterfeiting goods provisions do not apply to goods in transit in or being exported from Kenya. No other form of intellectual property protection is covered under this Act. This Act does not apply to civil trademark infringement matters such as confusingly similar goods, in particular confusing similar trade names derived from international non-proprietary names for medicines or confusingly similar trade dress or appearance (size, shape, and color) of medicines that are therapeutically equivalent.
APPENDIX I: List of Participants at the Technical meeting

<table>
<thead>
<tr>
<th>NAME</th>
<th>SEX</th>
<th>ORGANIZATION</th>
<th>E-MAIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allan Maleche</td>
<td>M</td>
<td>KELIN</td>
<td><a href="mailto:amaleche@kelinkenya.org">amaleche@kelinkenya.org</a></td>
</tr>
<tr>
<td>Catherine Kirk</td>
<td>F</td>
<td>UNDP</td>
<td><a href="mailto:catherine.kirk@undp.org">catherine.kirk@undp.org</a></td>
</tr>
<tr>
<td>Jecinta Nyachae</td>
<td>M</td>
<td>Aids Law Project</td>
<td><a href="mailto:jnyachae@aidslawproject.org">jnyachae@aidslawproject.org</a></td>
</tr>
<tr>
<td>Melba Katindi</td>
<td>F</td>
<td>KELIN</td>
<td><a href="mailto:mkatindi@kelinkenya.org">mkatindi@kelinkenya.org</a></td>
</tr>
<tr>
<td>Nelson Otwoma</td>
<td>M</td>
<td>NEPHAK</td>
<td><a href="mailto:notwoma@nephak.or.ke">notwoma@nephak.or.ke</a></td>
</tr>
<tr>
<td>Paul Ogendi</td>
<td>M</td>
<td>Aids Law Project</td>
<td><a href="mailto:paulogendi@gmail.com">paulogendi@gmail.com</a></td>
</tr>
<tr>
<td>Paulo Meireles</td>
<td>M</td>
<td>NEPHAK</td>
<td><a href="mailto:paulomeireles@me.com">paulomeireles@me.com</a></td>
</tr>
<tr>
<td>Rose Kaberia</td>
<td>F</td>
<td>ITPC</td>
<td><a href="mailto:rose@itpc-ea.or.ke">rose@itpc-ea.or.ke</a></td>
</tr>
<tr>
<td>Sangeeta Shashikant</td>
<td>F</td>
<td>Third World Network</td>
<td><a href="mailto:sangeeta@twnetwork.org">sangeeta@twnetwork.org</a></td>
</tr>
</tbody>
</table>

TECHNICAL MEETING ON THE PROPOSED AMMENDMENTS ON THE ANTI-COUNTERFEIT ACT IN REALTION TO ACCESS TO MEDICINES NOVEMBER 2013 IN MACHAKOS COUNTY, KENYA
Maanzoni Lodge - Athi River, Machakos County, Kenya

AGENDA

Monday, 25\textsuperscript{th} November 2013
Maanzoni Lodge

17:30 – 18:30 Arrival and registration of participants

19:00 – 21:00 Dinner at the lodge restaurant

Tuesday 26\textsuperscript{th} November 2013
Maanzoni Lodge

08:30 – 09:00 Session one: The Kenyan Experience on Anti-counterfeiting laws and access to medicines: Chair: Mr. Allan Maleche, Executive Director, KELIN (10min)

Preliminaries, (expectations and climate setting)

09:00 – 10:00 The Kenyan Experience on the Anti-counterfeit Act and Access to Medicines–Melba Katindi, Programme Officer KELIN (30min)

Discussion (20min)

10:15 – 10:45 REFRESHMENTS

10:45 – 12:45 Session Two –Overview of Anti-Counterfeiting Initiatives & TRIPS Provisions on Enforcement including definition of “Counterfeit”

Catherine Kirk – UNDP (20 min) and Sangeeta Shashikant, Third World Net work (40 min)

Discussion (40 min)

12:45 – 14:00 LUNCH

14:00 – 16:00 Session Three –Identifying Key Concerns in Kenya Anti-Counterfeit Legislation from A2M perspective & Development of Policy Brief and Position Paper. Chair: Rose Kaberia, Regional Director, ITPC – Eastern Africa (10 min)
Key legal concerns in the Kenya Anti-counterfeit Act that need to be amended Paul Ogendi, Deputy Director, AIDS Law Project (30 min)

**Commentator:** Sangeeta Shashikant, Third World Network (20 min)

Discussion on Identifying Amendments to the Kenyan Anti-Counterfeit Legislation. All participants (60 min)

<table>
<thead>
<tr>
<th>16:00 – 16:30</th>
<th>REFRESHMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>6:30 – 17:00</td>
<td>Discussion on Development of Policy Brief and CSO Position paper: All participants (30 min)</td>
</tr>
</tbody>
</table>

17:00 – 17:30 Closing remarks and briefing on the civil society forum to share outcomes of technical meeting - AIDS Law Project