Submissions on the provisions of the Anti-Counterfeit Act, 2008 that pose a threat on access to medicines in Kenya

Date of Submission: 13 October 2014
A. Introduction

1. KELIN is a human rights NGO working to protect and promote HIV-related human rights in Kenya. We do this by; providing legal services and support, training professionals on human rights, engaging in advocacy campaigns that promote awareness of human rights issues, conducting research and influencing policy that promotes evidence-based change.

2. KELIN makes these submissions jointly with the AIDS Law Project (ALP) and The National Empowerment Network of People living with HIV & AIDS in Kenya (NEPHAK) with endorsement from the undersigning organizations.

3. KELIN commends the Anti-Counterfeit Agency (The Agency) for its leadership in engaging stakeholders in the review process of the Anti-Counterfeit Act, 2008 on 25 September 2013 where we made oral submissions in this regard.

4. We submit that to the best of our knowledge, most of our submissions to the Anti-Counterfeit Agency during the review process have not been factored in the proposed amendments as tabled before the house in the Statutes Law Miscellaneous (Amendments) Bill, 2014 gazetted on 30 May 2014.

5. We hereby make comprehensive written submissions on the review of the Anti-Counterfeit Act, 2008 along with proposed amendments for consideration in drafting. We appreciate the opportunity to make this submission and to have our views heard.

B. Structure of submissions

The structure of the submissions is as follows:

I. Access to medicines as a fundamental component of the Right to Health in Kenya

II. The finding of the High Court of Kenya in 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)

III. Particulars of the Provisions of the Anti-Counterfeit Act 2008 that pose a threat to access to generic medicines

IV. Recommendations on Amendments

V. Conclusion

It is our Humble submission that:

I. Access to medicines is a fundamental component of the Right to Health in Kenya

6. In Kenya the right to health is provided for in the [Constitution of Kenya 2010](https://www.parliament.go.ke/Acts/Human-Rights-Constitution-2010.html). Article 43(1) states that “Every person has the right to the highest attainable standard of health”, which includes the right to health care services, including reproductive health care; to accessible and adequate housing, and to reasonable standards of sanitation; to be free from hunger, and to have adequate food of acceptable quality; to clean and safe water in adequate quantities; to social security; and to education. Further Article 43(2) provides that a person shall not be denied emergency medical treatment and Article 53(1)(c) makes provisions on the right to health care for children.

7. In framing the right to health, the Constitution adopted the right to the highest attainable standard of health recognized in regional and international human rights instruments. Additionally Article 2(6) provides that any treaty or convention ratified by Kenya shall forms part of the laws of Kenya.

8. Article 25(1) of the Universal Declaration of Human Rights (1948) states that “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.”

9. The International Covenant on Economic, Social and Cultural Rights (ICESCR) which provides the main foundation for legal obligations, in Article 12(1) states that governments recognize the “right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. Article 12(2) enumerates a number of steps to be taken by States parties to achieve the full realization of this right. In simplified language these include the right to:

   a. Maternal, child and reproductive health
   b. Healthy natural and workplace environments
   c. Prevention, treatment and control of disease
   d. Creation of conditions which would assure to all medical service and medical attention in the event of sickness including health facilities, goods and services.
10. In Para 12(a) of its General Comment Number 14 of May 2008 the Committee interprets the right to health, as defined in Article 12(1) of the Covenant, as an inclusive right, extending not only to timely and appropriate health care but also to the underlying determinants of health, such as access to safe water and sanitation, food, nutrition and housing, a healthy environment and health education and information. The right to health facilities, goods and services in Article 12(2)(d) includes appropriate treatment of prevalent diseases, preferably at community level; and the provision of essential drugs.

11. The right to health is also specifically provided for in Article 24 of the Convention on the Rights of the Child (CRC) of 1989 and Article 25 of the Convention on the Rights of Persons with Disabilities (CRPD) of 2006. Similarly Article 16 of the African Charter on Human and People’s Rights provides that ‘Every individual shall have the right to enjoy the best attainable state of physical and mental health’.

12. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), applicable in Kenya, sets out the minimum standards of protection in relation to Intellectual Property rights (IPRs) and describes the subject matter to be protected and the rights to be conferred including permissible exceptions to those rights.

13. The Doha Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference of 2001 reaffirmed the flexibility of TRIPS provisions to ensure better access to essential medicines. Paragraphs 4 to 6 of the Declaration require governments to protect public health and, in particular, promote access to medicines for all. The Declaration calls attention to the flexible solutions provided by the TRIPS Agreement to fight diseases such as HIV, tuberculosis and malaria and to assure that the necessary medicines are supplied.

14. The Industrial Property Act, 2001, brought the country into compliance with the TRIPS agreement. The debate that informed the passing of the Industrial Property Act was centered on the need to ensure access to medicines for Kenyans and saw the enactment of provisions that have since facilitated increased local production and international supply of generics which constitute about 90% of all medicines in Kenya.

15. The Kenyan parliament enacted the Anti-Counterfeit ACT No. 13 of 2008 (hereinafter referred to as the ‘ACT’), in order to ban trade in counterfeit goods as prescribed by the TRIPS Agreement. However, as currently enacted, the ACT runs contra to the aforesaid legal provisions and principles and thus poses serious threat to the right to health and access to medicines as it conflates generics with counterfeits. Of particular concern are the following two issues;


17. Structurally, Kenya has already established expert regulatory authorities established to determine intellectual property issues. The Kenya Industrial Property Institute (KIPI) is the Government parastatal established under the Industrial Property Act 2001 to administer industrial property rights. The Kenya Pharmacy and Poisons Board is the Drug Regulatory Authority established under the Pharmacy and
Poisons Act of the Laws of Kenya to regulate the Practice of Pharmacy and the Manufacture and Trade in drugs and poisons.

18. It is our humble submission therefore that regulation of medicines and pharmaceutical products should be excluded entirely from the provisions of this ACT.

II. The decision of the High Court of Kenya in relation to the Act in 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]

19. Our submissions under part I above are fortified by the recent decision of the constitutional division of the High Court in 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] which re-affirmed access to medicines as part of the right to the highest attainable standard of health.

20. In 2008 immediately after the enactment of the Anti-Counterfeit Act in Kenya, guided by the provisions in National, Regional and International law, the case of Patricia Asero Ochieng and 2 Others v. the Attorney General & Another was filed challenging the Constitutionality of Sections 2, 32 and 34 of the ACT as relates to access to generic medicines. The Petitioners were three persons living with HIV and relying on generic ARVs provided under government funded programs.

21. In particular, the petitioners argued that Section 2 of the Act confused generic drugs with counterfeit medicine and if implemented, the provisions of Sections 2, 32 and 34 of the Act would subject civil and criminal penalties on manufacturers and importers of generic medicines, hence severely restricting access to affordable medicine in Kenya. Such restrictions would violate the petitioners’ right to life, health and human dignity under Articles 26(1), 28 and 43 of the Constitution and Article 12 of the International Covenant on Economic, Social and Cultural Rights.

22. Access to medicines is a fundamental element of the right to health. This is the position of the UN special rapporteur on health, who was enjoined in this case as amicus curiae (a friend of the court) in fulfillment of his mandate in the United Nations Human Rights Council. In his submissions Mr. Anand Grover submitted that "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."

23. On 20 April, 2012 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 conflated 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.

24. The High Court ordered the state to reconsider the provisions of Section 2 of the Act alongside its constitutional obligations and make appropriate amendments to ensure that the rights of those dependent on generic medicines are not put in jeopardy.

25. To the best of our knowledge, understanding and belief the decision of the high court in this regard has not been appealed against and is still in force.

III. Particulars of the Provisions of the Anti-Counterfeit Act 2008 that pose a threat on Access to Generic Medicines in Kenya

a) “Counterfeiting” Definition Problem

26. As per definition in the ACT “goods that are identical or substantially similar” are counterfeits. Therefore this broad definition of counterfeits under the ACT can be used to restrict manufacture, sale and distribution of generic drugs in Kenya.

27. The use of the term “identical or substantially similar” and “colorable imitation” is problematic in the case of medicines, as medicines are intentionally identical in composition and, for clinical reasons, often also in appearance. The term “confusingly similar” is also problematic for medicines, as often the branding is derived from the International Nonproprietary Name (INN).

b) Criminal liability for acts of Counterfeiting

28. The penalties provided for offences under the Act are overly punitive as they impose criminal
sanctions on civil private rights that should be rightfully enforced individually using civil procedures. Trade-related disputes such as those related to counterfeiting are generally civil in nature, as opposed to criminal.

29. Fear of having a criminal claim brought under the Act is likely to discourage local Research and Development (R&D), the production, importation and exportation legitimate generics.

c) Powers of seizure and storage

30. The Act gives broad powers to the authorities to detain any goods suspected of being counterfeit and goes beyond the provisions outlined in the Constitution. Further, the Act does not provide specific timeframes within which the detained goods should be released even after the dispute is resolved. These broad powers given can be abused and may result in unwarranted delays and the deterioration of products especially public health sensitive provisions such as medicines or test kits which should not to be held for more than 10 days.

d) Application of the act to goods in transit

31. The provisions in this Act not only apply to goods in the Kenyan market but also to those in transit being imported to other countries in the region through Kenya. By enforcing this, authorities in Kenya will be utilizing public resources to enforce private rights of individuals based in other countries whereas these resources can be put to better use locally. This, therefore, extends all the above mentioned threats to the wider region, thus further threatening access to generic medicines beyond the Kenyan boundaries where such products may not be considered counterfeit.

e) Rules of evidence

32. The rules of evidence captured under Section 26 are unconstitutional for the reason that the defender is presumed guilty and the onus of proof is on them to prove otherwise.

f) Composition and operation of the board

33. The provisions of the Act allow private sector actors to be part of the Board. This raises serious concerns about conflicts of interest as they are likely to have strong commercial interests they wish to protect, and their involvement could conflict with the objectivity and independence of the Board. The provisions of this Act also allow the Board and the Anti-Counterfeit Agency to receive gifts, grants and donations from agencies other than the government which makes them susceptible/vulnerable to allegations of corruption.

IV. Recommendations on Amendments

For all the foregoing reasons, we propose the specific amendments as contained in the Annexure I of this document. The same are summarized as hereunder:

a) On the “Counterfeiting” Definition Problem:
   i. Limit the scope of the definitions of Counterfeit Goods in the Act to Counterfeit trademarks and Pirated copyright goods as defined in Article 51 of the Agreement on Trade Related Aspects to Intellectual Property Rights (TRIPS).

b) On Criminal Liability for acts of Counterfeiting:
   ii. Restrict criminal liability only to willful trademark or copyright piracy on a commercial scale as captured in Art 61 of the TRIPS agreement.

c) On Powers of Seizure and Storage:
   iii. Ensure legislative procedures are fair and equitable and in conformity with Constitutional and international human rights principles.
   iv. Provide reasonable timelines that limit unnecessary delays and suitable storage requirements especially for medicines.

d) On Application of the Act to Goods in Transit:
   v. Reflect on Article 60 of the TRIPS agreement which deals with De Minimis Imports and exempt small quantities of goods not imported for commercial use.
   vi. Limit border measures only to goods imported into and for use in Kenya.

e) On Rules of Evidence:
   vii. Procedures should conform to the strict provisions of the Constitution and the Evidence Act.
viii. The burden of proof should lie on the complainants to establish their rights as claimed before alleging violation.

f) On Composition and Operation of the Anti-Counterfeit Board (The Board):
ix. Ensure its membership encourages and operations uphold transparency of the board, minimize the probability of conflict of interest and include representation of consumer groups.

II. Conclusion

34. We reiterate our support for the amendment of the Anti-Counterfeit Act to the extent that the same will comply with the provisions of the Constitution of Kenya, 2010 as directed by the Commission on the Implementation of the Constitution and issued by the Head of Public Service on 20 April 2011 by way of Circular No. OP.CAB.17/84/1A and the judgment of the High Court of Kenya in the Patricia Asero case to ensure access to life saving generic medicines. The legal environment should be supportive of life saving generic pharmaceuticals which are vital to health care delivery in Kenya because of their affordability and availability.

35. We strongly caution against the misguided perception that stronger IP protection will ensure quality medicines in Kenya. On the contrary, this is most likely to hamper the local manufacture, production and packaging of generic medicines envisioned on the Pharmaceutical Manufacturing Plan for Africa (PMPA) endorsed by African Heads of State and Governments at the summit in Accra in 2007.

36. Quality of medicines is non-negotiable and must be assured through strict application of Good Manufacturing Practices (GMP) and other quality assurance practices. To this end we urge the government to explore genuine solutions to address the high prices of medicines and strengthen the pharmaceutical regulatory capacity in Kenya through the relevant existing legal and structural framework.

37. In light of the discussions and recommendations contained in these submissions, we call upon the relevant policy makers to amend the provisions of the Anti-Counterfeit Act and take all necessary measures to ensure access to affordable and essential medicines including generic medicines in compliance with the judgment of the High Court of Kenya.

We thank you for the opportunity to make these submissions for your kind consideration in amending the Anti-Counterfeit Act. We have attached our proposed specific amendments for you further information and kind consideration in re-drafting.
PROPOSED AMENDMENTS TO THE ANTI-COUNTERFEIT ACT, 2008

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<tr>
<th>CURRENT WORDING OF SECTION</th>
<th>PROPOSED AMENDMENTS</th>
<th>REMARKS/ JUSTIFICATIONS</th>
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<tr>
<td>“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-</td>
<td>We propose the following specific amendment to Section 2: “Counterfeiting” means acts done willfully and on a commercial scale in relation to counterfeit trademark goods and pirated copyright goods. Where -</td>
<td>The scope of the current definition is too broad. The use of the term “in Kenya or elsewhere” in the definition enables claims of Intellectual Property (IP) right recognized in other countries outside of Kenya without the right being specifically protected by an IP legislation in Kenya.</td>
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<td>(a) the manufacture, production, packaging, re-packaging, labeling 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;</td>
<td>a) &quot;Counterfeit trademark goods&quot; refer to 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;</td>
<td>The proposed amendment is in line with Article 51 and Article 61 of the TRIPs Agreement.</td>
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<td>(b) the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a colorable 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 license;</td>
<td>b) &quot;Pirated copyright goods&quot; refer to 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;</td>
<td>The proposed definition of Counterfeit trademark goods and Pirated copyright goods is drawn from footnote 14 of Article 51 of the TRIPs Agreement.</td>
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<td>(c) the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author’s rights or related rights;</td>
<td>c) Counterfeiting under this Act shall not apply to goods in transit or being exported from Kenya.</td>
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<td>(d) in relation to medicine, the deliberate and fraudulent mislabeling 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;</td>
<td>d) No other form of intellectual property protection is covered under this Act and provisions under this Act shall 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 colour) of medicines that are therapeutically equivalent.</td>
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Provided that nothing in this paragraph shall derogate from the existing provisions under the Industrial Property Act.
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<td>“counterfeit goods” means goods that are the result of counterfeiting, and includes any means used for purposes of counterfeiting; “intellectual property right” includes— (a) any right protected under the Copyright Act; (b) any plant breeders’ right granted under the Seeds and Plant Varieties Act; (c) any right protected under the Trade Marks Act; and (d) any right protected under the Industrial Property Act;</td>
<td>Delete</td>
<td>With the above amendment of “counterfeiting”, there is no need for a definition of counterfeit goods”, “intellectual property” or “protected goods” because the scope of this Act becomes clear. This will exclude the rights protected under the Industrial Property Act and the Seeds and Plant Varieties Act, which are currently included.</td>
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<td>protected goods” means— (a) goods featuring, bearing, embodying or incorporating the subject matter of an intellectual property right with the authority of the owner of that intellectual property right, or goods to which that subject matter has been applied by that owner or with his authority; (b) any particular class or kind of goods which, in law, may feature, bear, embody or incorporate the subject matter of an intellectual property right only with the authority of the owner of that intellectual property right, or to which that subject matter may in law be applied, only by that owner or with his authority, but which has not yet been manufactured, produced or made, or to which that subject matter has not yet been applied, with the authority of or by that owner, whichever is applicable;</td>
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## PART TWO – ESTABLISHMENT POWERS AND FUNCTIONS OF THE AGENCY

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<td>Section 6 Board of the Agency</td>
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<td>The inclusion of the private sector actors raises serious concerns about conflict of interest as they have strong commercial interests which they wish to protect and their involvement could conflict with the objectivity and independence of the board.</td>
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<td>(1) The management of the Agency shall vest in a board which shall consist of –</td>
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<td>(k) The chief executive of the Kenya Association of Manufacturers or his representative</td>
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<td>Delete Section sub-para (d)</td>
<td>The agency should only be funded by the government and should not be allowed to receive any other contributions or gifts especially from private sector actors. This will eliminate vulnerability or susceptibility of corruption allegations and promote objectivity.</td>
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<td>Section 7 Powers of the Board</td>
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<td>The Board shall have all powers necessary for the proposer performance of its functions under this Act and in particular, but without prejudice to the generality of the foregoing, the board shall have power to –</td>
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<td>(d) receive any grants, gifts, donations or endowments on behalf of the agency and make legitimate disbursements therefrom</td>
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## PART FOUR – INSPECTION

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<td>Section 23 Powers of Inspectors</td>
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<td>This Section is unconstitutional. Section 40(2) of the Kenya Constitution states: (2) Parliament shall not enact a law that permits the State or any person— (a) to arbitrarily deprive a person of property of any description or of any interest in, or right over, any property of any description;</td>
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<td>Inspectors should only be allowed to exercise powers under Section 23 upon a court issuing a warrant</td>
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<td>Section 25 (3) and (4) Duty of inspector upon seizure of goods</td>
<td>A reasonable time-frame should be allocated within which the Court should make a determination.</td>
<td>It is only fair that there is a time frame within which the Court should make a determination. Without a time frame, court proceedings could continue indefinitely. In determining the time frame it should also be considered that the goods may be perishable.</td>
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<td><strong>Section 26</strong></td>
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<td>(5) Where the subsistence of</td>
<td>Where the existence of</td>
<td>It should be the task of</td>
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<td>intellectual property right in respect of suspected counterfeit goods or the title or interest in intellectual property right is in issue, the complainant shall be presumed to be the owner of the copyright of related right or, as the case may be, the exclusive licensee of any such right, until the contrary is proved</td>
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**PART FIVE – COUNTERFEIT GOODS**

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<th>Section 32</th>
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<th>The current Section 32 is TRIPS plus. It will implicate those that unknowingly deal with counterfeit goods. Further the prohibition extends to goods in transit/transshipped and those exports from Kenya. Such a provision has extensive implications for Kenya as it will have to spend significant resources in dealing with counterfeit goods that are not intended for use in Kenya. This means Kenya will be utilizing its resources to extend its jurisdiction by applying its law to goods destined for other countries; whether or not they have similar IP protection. With these types of provisions, other countries, especially the least developed countries in the region, may refuse to use Kenya as a transit port, which may entail significant trade loses for Kenya.</th>
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<td>It shall be an offence for any person to willfully and on a commercial scale: manufacture, produce or make any counterfeit trademark good or pirated copyright goods; sell, hire out, barter or exchange, or offer or expose for sale, any counterfeit trademark good or pirated copyright goods; expose or exhibit any counterfeit trademark good or pirated copyright goods; distribute any counterfeit trademark good or pirated copyright goods; import any counterfeit trademark good or pirated copyright goods. Section 32 should also make provision for de minimis imports (minor/insignificant quantities) as allowed by Article 60 of the TRIPS Agreement. Article 60 of the TRIPS Agreement states: “Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers’ personal luggage or sent in small consignments.”</td>
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<td>Section 32 should only apply in cases where an act is done willfully or on a commercial scale and should NOT extend to goods in transit/transshipped and exports from Kenya.</td>
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<td>Section 34 Powers of the Commissioner</td>
<td>Rights of the defendant (to whom the detained goods belong) should be spelt out clearly.</td>
<td>It is unclear what happens to the goods that are detained under Section 34. In particular the rights of the defendant (to whom the detained goods belong) with regard to the timeframe within which the court must make a determination that the goods are counterfeit and if they are not counterfeit then the goods should be released. In this regard, due note should be taken of Article 55 of the TRIPS Agreement which states the following: Duration of suspension: “If, within a period not exceeding 10 working days after the applicant has been served notice of the suspension, the customs authorities have not been informed that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods, the goods shall be released, provided that all other conditions for importation or exportation have been complied with; in appropriate cases, this time-limit may be extended by another 10 working days. If proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified, revoked or confirmed. Notwithstanding the above, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, the provisions of paragraph 6 of Article 50 shall apply.”</td>
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OTHER COMMENTS

There are various provisions under the Act that authorize the inspectors/customs officials to act on their own initiative. IP rights are private rights and should rightfully be enforced by a rights holder with valid grounds. Where the right holder of the IP is not interested in pursuing the case, the inspectors/customs officials should not be authorized to act suo moto – action taken by the authority without formal complaint by the owner.

The Act is about criminal disputes initiated by the Agency. But then Section 26 (2), (4) and (8) refers to civil proceedings. It is unclear which disputes under the Act are civil disputes. Further if civil disputes are covered by this legislation, then what types of disputes are covered under other IP laws in the country?
Notes
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