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Striking a Balance between Protecting Trademarks and Public Health Interests in Combating Trade in Counterfeit Medicines: Lessons from Kenya and South Africa

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Abstract

Trade in counterfeit medicines raises serious public health concerns. However, efforts geared towards combating trade in counterfeit medicines tend to focus more on the protection of trademarks, which may not necessarily protect the public from the adverse consequences of using counterfeit medicines. This arises from differences in the meaning of "counterfeit" in the intellectual property and public health contexts. This article analyses the extent to which the anti-counterfeiting legislation and institutions in two African countries, Kenya and South Africa, are capable of combating trade in counterfeit medicines in a manner that protects both the public and brand name owners. The article examines the anti-counterfeiting legislation and institutions that ensure compliance with the standards for marketing medicines that are in place in these countries, in order to draw lessons on how they can be used to balance the protection of public health interests and trademarks.

Keywords

Counterfeit medicines, intellectual property, Kenya, public health, South Africa, trademarks

INTRODUCTION

The word "counterfeit" has different meanings in the public health and intellectual property (IP) contexts. In the public health context, it is "used in the broadest sense and should not be confused with trademark infringement".[1] Musungu

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1 World Health Organization / World Intellectual Property Organization / World Trade Organization "Promoting access to medical technologies and innovation: Intersections between public health, intellectual property and trade" (2013) at 70.

observes that the definition of "counterfeit" or "counterfeiting" has raised serious concerns in the ongoing initiatives in the East African Community (EAC) and elsewhere. He points out that this is mainly because the term "has both a technical IP meaning (as defined in the TRIPS Agreement) and a common usage as in fake".[2]

The definition, which the World Health Organization (WHO) agreed jointly with the International Federation of Pharmaceutical Manufacturers & Associations in 1992, seems to focus more on issues such as the safety and efficacy of medicines, while article 51 of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) focuses more on the protection of trademarks. This is understandable because article 51 stipulates border measures that WTO member states should put in place to combat the trans-boundary infringement of IP. WHO defined counterfeit medicines[3] as medicines that are: "deliberately and fraudulently mislabelled with respect to identity and / or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients without active ingredients, with insufficient active ingredients or with fake packaging".[4]

This definition focuses on both trademark infringement as well as safety related matters such as drug ingredients and manufacturing standards. The definition has been the subject of debate and there is currently no agreed definition in the context of medicines, due to the reasons explained in the next part of this article. The definition has mixed medicine safety with trademark infringement. Nevertheless, it shows the need for directly involving public institutions that set standards for manufacturing and marketing medicines in efforts towards combating trade in counterfeit medicines. The definition contrasts with the definition of counterfeit trademarks in article 51, footnote 14 (a) of TRIPS, which describes counterfeit trademarks as: "any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered 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 question under the law of the country of importation". It is clear that this definition is limited to trademarks and does not include other types of intellectual property rights (IPRs).

The trilateral study by WHO, the World Intellectual Property Organization (WIPO) and WTO has observed that combating trade in substandard and spurious / falsely-labelled / falsified / counterfeit (SSFFC) medical products in the

2 SF Musungu "The potential impact of the proposed East African Community (EAC) anti-counterfeiting policy and bill on access to essential medicines" (UNDP BDP HIV practice discussion paper, March 2010) at 11.

3 WHO has since changed the terminology to spurious / falsely-labelled / falsified / counterfeit medicines; see WHO "Medicines: Spurious / falsely-labelled / falsified / counterfeit (SFFC) medicines" (fact sheet no 275, May 2012), available at: <http://www.who.int/mediacentre/factsheets/fs275/en/> (last accessed 12 November 2013).

4 WHO Department of Essential Drugs and Other Medicines "Counterfeit drugs: Guidelines for the development of measures to combat counterfeit drugs" (1999) at 7.

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context of public health "is exclusively motivated by the threat to public health, and related concerns about consumer protection [while] from an IP perspective, using a trademark commercially without the authorization of its owner is the key condition to consider a product as counterfeit".[5] Much as IP enforcement is aimed at enforcing the rights of trademark owners, the study does concede that public interests are equally protected through such an enforcement mechanism, particularly in the fight against criminal infringement.[6] This concession provides the basis for exploring the possibility of using IP enforcement as an appropriate tool for achieving public health objectives. This is the case since "trademark owners have strong incentives to ensure that the quality of their product is maintained because their reputation and hence their future profitability depends upon it".[7]

There are indeed points of convergence between the criminal infringement of trademarks and the protection of public health. It is in anticipation of such convergence that the trilateral study proposed, inter alia, the use of criminal law along with collaboration between legislative bodies and enforcement agencies, as well as enforcement of good manufacturing practice standards as means to tackle the steady increase in SSFFC medical products.[8]

Opinion is however divided on using IP enforcement to achieve public health goals.[9] This is evident in the circumstances leading to the establishment of the new mechanism for collaboration among WHO member states discussed later in this article, which reckons with these divided opinions and proposes ways of reconciling them with a view to promoting IP enforcement as a tool for protecting public health interests.

It should be noted that the problem of counterfeit medicines, as Tremblay argues, is caused by "patterns of behaviour and medicines use as well as health policy, commercial strategies and regulatory practices and their unintended incentives".[10] This argument makes considerable sense, particularly in view of the widespread confusion between counterfeit and generic medicines. The confusion is more evident in the ongoing developments in the EAC, as well as the anti-counterfeit legislation in both Kenya and South Africa.

Notably, the WHO guidelines mention the fact that "disregard of trademarks rights may encourage large scale counterfeiting of drugs".[11] Consequently, by advocating an approach that strikes a balance between

5 WHO / WIPO / WTO "Promoting access to medical technologies", above at note 1 at 70.
6 Ibid.
7 J Morris and P Stevens "Counterfeit medicines in less developed countries: Problems and solutions" (International Policy Network, 2006) at 5.
8 WHO / WIPO / WTO "Promoting access to medical technologies", at note 1 at 11.
9 WIPO "International exhaustion and parallel importation", available at: <http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm> (last accessed 16 June 2014).
10 M Tremblay "Medicines counterfeiting is a complex problem: A review of key challenges across the supply chain" (2013) 8/1 *Current Drug Safety* 43 at 44.
11 WHO "Counterfeit drugs", above at note 4 at 16.

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protecting public health interests and trademarks, this article acknowledges the important role of trademarks, which play an important role in distinguishing brand name owners' products from those of competitors in the same market. Combating trade in counterfeit medicines is a complex issue such that "relying on IP enforcement to ensure quality is a flawed approach … because poorly conceived anti-counterfeiting laws and regulations can undermine public health by targeting legitimate generic medicines".[12] This article will show the extent to which the proposed anti-counterfeiting legislation in the EAC and the legislation in force in Kenya and South Africa are flawed. A more strategic approach is therefore needed, as proposed in this article.

Tremblay, for instance, suggests linked strategic responses in five areas: logistics, regulation / laws, dispensing / use, manufacture / packaging, and information integration. Tremblay however concedes that "these strategic aspects … are unlikely to stop the incentive to produce illegal or counterfeit products when a market for these products may continue to exist owing to how medicines are priced or supplied".[13] He suggests that the problem requires "whole-systems thinking". It should be noted that anti-counterfeiting legislation targets third parties. Consequently, it does not cover IPR owners that produce substandard medicines.[14] Although this is a concern that may impact negatively on public health, the limited scope of this article does not warrant including a discussion of such parties and the substandard medicines that they produce. The article therefore focuses on counterfeit medicines from a technical IP perspective.

The first part of the article provides general information on the WHO member state mechanism, which has been established to combat SSFFC medicines. It considers the process leading to the establishment of this mechanism and its mandate, with a view to establishing the extent to which public health interests can be dealt with appropriately while combating trade in counterfeit medicines. The second part critically analyses the legal regimes in Kenya and South Africa. In view of the great influence that these two countries have had on the EAC's approach to counterfeiting, current developments in the East African region, particularly through the EAC, are discussed in the third part. The fourth part considers how lessons drawn from the two countries can be used to balance the protection of public health interests and trademarks.

12 J Brant and R Malpani "Eye on the ball medicine regulation - not IP enforcement - can best deliver quality medicines" (2 February 2011) 143 *Oxfam Briefing Paper* at 22.

13 Tremblay "Medicines counterfeiting", above at note 10 at 48.

14 J von Braun and P Munyi "New enforcement mechanisms challenge the legality of generics in the name of public health: The emergence of anti-counterfeiting legislation in East Africa" (2010) 18 *African Journal of International and Comparative Law* 238 at 247.

THE WHO MEMBER STATE MECHANISM

The WHO's initial collaborative initiative in counterfeiting activities was through the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), which included "WHO, the multinational pharmaceutical industry, Interpol, the European Commission, various intergovernmental organizations and representatives of the health-care sector".[15] Its mandate was to develop global solutions to the global problem of counterfeit medical products.[16] Several WHO member states expressed concerns about the controversial nature of IMPACT's work, due to the apparent confusion between public health goals and commercial interests.[17] In particular, WHO's mandate and legitimacy were questioned in relation to its role in IP enforcement.[18] The WHO director general insisted however that WHO's collaboration in the taskforce had no role in IP enforcement.[19]

The specific concerns, raised by member states in contesting WHO's involvement in IMPACT, are quite informative on the issues that require critical consideration when using IP enforcement for advancing public health goals. The main concern related to the definition of "counterfeit". In this regard, member states raised the issue of "whether the WHO should use the term 'counterfeit' - which is defined in the TRIPS Agreement as referring to a specific category of trademark violation - to also refer to medical products of compromised quality, safety and efficacy".[20] It was specifically pointed out by developing countries, led by Brazil, that dealing with counterfeits should be within the mandate of WTO and WIPO, and that WHO should limit itself to falsified medicines.

Member states also viewed as confusing WHO's broad definition of counterfeit, which goes beyond TRIPS by referring to both trademarks and safety related matters, as it leads to quality issues being considered from an IP perspective.[21] As a result of these concerns, WHO decided to continue using the term "substandard / falsified / spurious / counterfeit" medical products until agreement is reached.[22]

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15 Brant and Malpani "Eye on the ball medicine regulation", above at note 12 at 32; for the origins, legitimacy, transparency and accountability of IMPACT, see KM Gopakumar and S Shashikant *Unpacking the Issue of Counterfeit Medicines* (2010, Third World Network (TWN)), chap 4.

16 Brant and Malpani, ibid.

17 WHO "Report of the working group of member states on substandard / spurious / falsely-labeled / falsified / counterfeit medical products" (A/SSFFC/WG/5, 11 March 2011), para 19.

18 GL Burci "Public health and 'counterfeit' medicines: The role of the World Health Organization" (2013) 17/2 *American Society of International Law Insights* 7.

19 TWN "Clash over WHO's role in 'counterfeits', IMPACT" (25 May 2010) *TWN Information Service on Health Issues*, available at: <http://www.twn.my/title2/health.info/2010/health20100505.htm> (last accessed 26 November 2015).

20 Ibid.

21 Ibid.

22 Ibid.

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Developing countries eventually rendered IMPACT dormant when they won the adoption of the 2010 World Health Assembly resolution A63/23 for the formation of an intergovernmental commission, tasked with examining WHO's "role in ensuring availability of good-quality, safe, efficacious and affordable medicine; relationship with … IMPACT; and role in prevention and control of [SSFFC] medical products".[23]

The result of the commission's work is resolution WHA 65.19, under which WHO established "a new Member State mechanism for the international collaboration among Member States, from a public health perspective".[24] The mandate of this mechanism excludes trade and IP considerations. It started work in November 2012 and will be reviewed after three years of operation.[25]

Member states are urged to participate and collaborate with the mechanism on a voluntary basis and to provide financial support. One of the mechanism's goals is to "further develop the definitions of SSFFC medical products that focus on the protection of public health".[26] The mechanism should reckon with suggestions, which authors such as Brant and Malpani had put forward before IMPACT became dormant, urging WHO to "acknowledge that it has created unnecessary confusion through misusing the term counterfeit to refer to substandard and falsified medicines that are unrelated to trademark infringement, and through the use of an IP framework to evaluate the public health problem of unsafe medicines".[27] Such suggestions are helpful for providing the context for the debatable observation made in the abstract to this article that focusing more on the protection of trademarks may not necessarily protect the public from the adverse consequences of using counterfeit medicines. It is worth exploring this point at this stage.

As noted already, the word counterfeit has different meanings in the IP and public health contexts. If IP enforcement is to be used appropriately to combat trade in counterfeit medicines, then the limitations of this approach must be taken into account. Musungu has, for instance, argued that "because substandard products relate to what are considered 'genuine' products, an IP enforcement-based approach to medicines quality is likely to result in totally ignoring this major problem".[28] On the same point, Brant and Malpani have suggested that a functioning drug regulatory authority (DRA), rather than IP enforcement, is better placed to protect the public comprehensively from poor quality and falsified medicines. They conclude that "anti-counterfeiting actions based on trademark enforcement should be narrowly targeted and

23 WHO "Sixty-third World Health Assembly closes after passing multiple resolutions", available at: <http://www.who.int/mediacentre/news/releases/2010/wha_closes_20100521/en/> (last accessed 15 June 2014).
24 WHA65/2012/REC/1, para 4.
25 Id, para 5.
26 Id, paras 6(1) and 6(2).
27 Brant and Malpani "Eye on the ball medicine regulation", above at note 12 at 38.
28 Musungu "The potential impact", above at note 2 at 22.

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supplementary to regulation by health authorities".[29] The views of these authors are useful in appreciating the real issues at stake in attempting to use IP enforcement as a tool for protecting public health interests in relation to counterfeit medicines.

Interestingly, the Kenya Pharmacy and Poisons Board (PPB) has indicated how difficult it is to discover counterfeit medicines during product registration, as such medicines are never registered.[30] This shows that, to combat trade in counterfeit medicines effectively, the DRAs need to work closely with anti-counterfeiting law enforcement authorities. Consequently, it is inevitable that IP enforcement will be used as an appropriate tool for protecting public health. The subsequent parts of this article focus on the anti-counterfeiting laws and institutions currently used in Kenya and South Africa, with a view to highlighting the extent to which IP enforcement regimes in these countries are capable of being used as appropriate tools for protecting public health interests. Considering how new the WHO member state mechanism is and the limited period that it has been in existence, the lessons drawn from these African countries can also be useful in achieving the mechanism's goal of protecting public health.

LEGAL AND INSTITUTIONAL FRAMEWORKS FOR COMBATING TRADE IN COUNTERFEIT MEDICINES IN KENYA AND SOUTH AFRICA

This section considers the frameworks in Kenya and South Africa before dealing with the current trends in East Africa for two reasons. First, some of the countries in the sub region, for instance Tanzania, have only amended their laws or, such as Uganda, still have bills pending, while Kenya has enacted a specific law to deal with counterfeits based on prior consultations with South Africa. Kenya's legal framework has therefore influenced current developments in East Africa. Secondly, the Kenyan and South African regimes have been judicially tested and the rich jurisprudence from both countries is suitable for evaluating the suitability or otherwise of the current policy and legal frameworks that are being developed in East Africa.

Although many laws come into play in regulating trade in counterfeits, the limited scope of this article only warrants consideration of the anti-counterfeiting legislation and legal frameworks governing the operations of the DRAs that are in place in the two countries to ensure compliance with standards in the manufacturing and marketing of medicines.

29 Brant and Malpani "Eye on the ball medicine regulation", above at note 12 at 22.

30 Presentation by Dr Jayesh M Pandit (head of Department for Pharmacovigilance, PPB) "Scope of local (anti) counterfeit problem in Kenya" (13 February 2008), cited in E Tai (2011 Pfizer global health fellow) "Counterfeit medicines in Kenya", available at: <http://www.pfizer.com/files/responsibility/global_health/elaine_tai.pdf> (last accessed 9 June 2014).

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The frameworks in Kenya

The Anti-Counterfeit Act[31]

This act was enacted in 2008 and established the Anti-counterfeit Agency (ACA). The agency's functions are, inter alia, to combat counterfeiting trade and other dealings in counterfeit goods in Kenya in accordance with the act. It also coordinates with national and international organizations involved in combating counterfeiting.[32] ACA is relatively new as it started operating in 2010.

Section 33(1) of the act provides that a holder of IP may report suspected trade in counterfeit goods, which is an offence under section 32, to the agency's executive director. On receiving such a complaint, the executive director checks the information provided by the IP holder in order to satisfy himself that, prima facie, the goods are counterfeit. Assuming this is the case, steps are taken under section 23(1), which empowers an inspector to search suspected premises or vehicles with a view to terminating the manufacturing, production or making of counterfeit goods. It is worth noting that seized goods can only be destroyed if authorized by an order of a competent court.[33]

The procedure to be followed by IP owners who are affected by the importation of counterfeits is stipulated in section 34 of the act. Applications in this case are made to the commissioner of the Kenya Revenue Authority. Subsection 3 requires the commissioner to consider and deal with an application within a period of three working days. If an application is granted, the affected goods may be seized and detained by customs authorities under section 34(4). A party who suffers damage due to the wrongful seizure, removal or detention of goods can claim compensation from the applicant if the seizure or detention was false, negligent or made in bad faith.

Counterfeiting was previously defined in section 2 of the act as taking any of the actions listed in paragraphs (a) to (d) of that section without the authority of the owner of the IPR subsisting in Kenya or elsewhere in respect of protected goods. The relevant acts are manufacturing, production, packaging, repackaging and labelling. This provision can be contrasted with the Ugandan bill, which refers to IPRs in Uganda, not elsewhere.[34] The word "elsewhere" has since been deleted from the Kenyan legislation through an amendment, which brought the Anti-Counterfeit (Amendment) Act 2014 into force on 28 November 2014 when the bill received presidential assent.[35]

Goods are defined in section 2 of the Kenyan act as "goods that are the result of counterfeiting, and includes any means used for purposes of counterfeiting". With regard to medicines, section 2(d) describes counterfeiting as: "…

31 Act no 13 of 2008.
32 Sec 5.
33 Sec 23(1)b.
34 The Ugandan Anti-Counterfeiting Bill 2010, sec 2.
35 Statute Law (Misc Amendments) Bill, 2014, amendments to the Anti-Counterfeiting Act, secs 2, 6, 16 and 34.

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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".

This section was inserted into the act for the purpose of exempting medicines from the general definition of counterfeit goods, since critics had raised concerns that the general definition was so wide that it would include genuine generic medicines. However, this definition did not remedy the problem. Besides, it simply adopts the contested WHO definition. This position is evident from the fact that the section focuses more on the identity or source, which are usually demarcated through trademarks, in determining whether or not the medicines are counterfeit, irrespective of the safety or authenticity of the ingredients. In contrast with the TRIPS definition, the section is not limited to trademarks but takes an approach that leans towards a substantive expansion of the subject matter of counterfeiting by referring to IPRs in general. This means that patents and any other IPRs are covered by this legislation. In this regard, generic medicines can fall within the scope of the definition so long as they bear some resemblance to the original branded medicine in their labels and even in their chemical substance.

The broad scope of IPRs included in the definition of counterfeiting also seems problematic, particularly when considered alongside section 15A of Kenya's Trademarks Act,[36] which limits the scope of trademarks that subsist elsewhere but are protected in Kenya by virtue of their being "well-known", as defined in that section. Notably, the section simply repeats the international norms relating to the protection of well-known trademarks that are provided for under the Paris Convention for the Protection of Industrial Property of 1883, without adding any requirements to be satisfied at the national level. This approach can be contrasted with section 35(1A) of the South African Trademarks Act, which specifically provides for local criteria: "due regard shall be given to the knowledge of the trade mark in the relevant sector of the public, including knowledge which has been obtained as a result of the promotion of the trade mark". In view of the low threshold for the protection of well-known trademarks in Kenya, section 2 of the Anti-Counterfeit Act may create a loophole through which holders of trademarks, which meet the general requirements of section 15A of the Trademarks Act, may take refuge under the Anti-Counterfeit Act to enforce rights that may not meet the other requirements for protection under the Trademarks Act. This undesirable situation will only be remedied once the pending proposed amendment to the act has come into force.

These sections of the Anti-Counterfeit Act were challenged in the Constitutional Court for being so broad as to include generic medicines in the definition. The case of *PAO and 2 Others v Attorney General*[37] (*PAO*) highlights the adverse consequences of such a broad definition. The petitioners in this

36 Chap 506.

37 [2012] eKLR, decided 20 April 2012.

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case were adults who had been living with HIV for between eight and 19 years. For about ten years, they had been taking generic anti-retroviral HIV drugs, which had become widely available following the enactment of the Industrial Property Act.[38] The sale of generic medicines became possible in Kenya when section 58(2) of the Industrial Property Act, read with rule 37 of the Industrial Property Regulations of 2002, allowed the parallel importation of such medicines.

The petitioners' case was that the enforcement and application of the Anti-Counterfeit Act "particularly sections 2, 32 and 34 will endanger their well being as they will be arbitrarily denied access to affordable and essential drugs and medication necessary for the fulfillment of the necessary quality of life, human dignity and health guaranteed under Articles 26(1), 28 and 43 of the Constitution".[39] They argued that the government had failed to exempt generic medicines from the definition of counterfeit goods in the act, in so far as counterfeit goods were "defined in the section in such a manner as would allow generic drugs to be included in the said definition thereby effectively prohibiting importation and manufacture of generic drugs and medicines in Kenya".[40] The petitioners' case resonates with concerns, also raised in other East African countries, that "confusion of legal terms provides legal uncertainty on the status of generic drugs".[41]

In handing down a judgment in favour of the petitioners, the court noted that the state's obligation to protect the right to health "encompasses not only the positive duty to ensure that its citizens have access to health care services and medication but must also encompass the negative duty not to do anything that would in any way affect access to such health care services and essential medicines".[42] The court further emphasized that "any legislation that would render the cost of essential drugs unaffordable to citizens would thus be in violation of the state's obligations under the Constitution".[43] It was thus held that the Anti-Counterfeit Act "severely limits or threatens to limit access to affordable and essential drugs and medicines including generic medicines"[44] and that the state should reconsider the provisions of section 2 in view of "its constitutional obligation to ensure that its citizens have access to the highest attainable standard of health".[45] The court also held that the act infringed the "petitioners' right to life, human dignity and health guaranteed under Articles 26(1), 28 and 43(1) of the Constitution".[46] The court's views

38 Act no 3 of 2001.
39 *PAO*, para 10.
40 Id, para 14.
41 von Braun and Munyi "New enforcement mechanisms", above at note 14 at 247.
42 *PAO*, para 66.
43 Ibid.
44 Id, para 87.
45 Id, para 88.
46 Id, para 87.

show the importance of considering public health issues in combating trade in counterfeit medicines through anti-counterfeiting legislation.

It would appear that the Anti-Counterfeit Act was enacted in response to concerns, raised previously, that weak law enforcement has encouraged counterfeiting in Kenya. Mbogo for instance reported that the Kenyan government spends US$64.5 million on counterfeit medicines, while convicted counterfeiters only pay a fine of US$80![47] Unfortunately, as the court correctly noted in *PAO*, the act failed to focus on protecting consumers from counterfeit medicines, as there is no emphasis on standards and quality.[48] A close look at the Anti-Counterfeit Regulations[49] reveals that they merely deal with procedural issues that are geared towards protecting the interests of IP owners, rather than of consumers. Apart from this very well decided case, commentators have highlighted other serious weaknesses in the act. For example, it gives too much power to the Kenya Revenue Authority officials who are now faced with the technical task of establishing whether drugs are genuine or counterfeit, yet the PPB is the competent body that should perform such a task.[50] This essentially means that the technical means of combating counterfeiting will not be used, which makes the enforcement mechanism rather weak. This argument is supported by the fact that the available technical resources are not channelled, through the act, to ascertaining the safety and efficacy of medicines that are suspected of being counterfeit. One can envisage a situation where counterfeit medicines that do not contain any beneficial ingredients may end up being released into the supply chain simply because ACA has established that there is no deliberate and fraudulent mislabelling.

Institutional frameworks that ensure compliance with standards

A number of statutory bodies have been established in Kenya to regulate standards and the quality of pharmaceutical products. The two bodies that are relevant for the purposes of this article are the PPB and the Kenya Bureau of Standards.

The PPB was established under section 3 of the Pharmacy and Poisons Act.[51] It is responsible for registering pharmaceutical products, after evaluating their efficacy, safety and quality. The board is also responsible for ensuring compliance with professional ethics by manufacturers and pharmacists. In this regard, the board has issued a Code of Promotional Practices for

47 S Mbogo "Why we are losing the war against fake drugs" (1 May 2008) *Business Daily*, available at: <http://allafrica.com/stories/200805010751.html> (last accessed 10 October 2013).

48 *PAO*, para 82.

49 The Anti-Counterfeit Regulations (2010) Legislative Supp No 36.

50 S Anyangu-Amu "Anti-Counterfeit Act violates right to health, say patients" (23 December 2009) *Business Daily*, available at: <http://www.businessdailyafrica.com/Corporate-News/-/539550/829374/-/14yc85dz/-/index.html> (last accessed 7 October 2013).

51 Chap 244.

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Pharmaceutical Representatives in Kenya. This code domesticated the International Code for Promotion of Pharmaceuticals and prescribes the ethical standards that should be followed in promoting pharmaceutical products. Paragraph 8.3 of the Kenyan code requires promotional information to be "capable of substantiation either by … reference to approved labelling or by scientific evidence". Section 2d of the Anti-Counterfeit Act should reckon with the existence of such ethical requirements by empowering the board to enforce compliance. This suggestion is made in view of concerns that have been raised that, in practice, the board lacks the statutory power to enforce codes of ethics and has insufficient human resource capacity to handle illegal and unethical activities such as counterfeiting.[52] The board's functioning could be improved if it were empowered to work closely with ACA by replacing the current wording of section 2d with a proviso to section 2, that the board should determine whether or not medicines are counterfeit. The board could then advise ACA on how to handle allegations of counterfeiting in relation to medicines.

The Kenya Bureau of Standards was established under section 3 of the Standards Act of 1973. It provides the government with services that may be required to test the standards of locally manufactured or imported commodities with a view to establishing their compliance with prescribed quality standards.[53] This body's mandate clearly requires coordination and information sharing with other institutions for it to maintain standards. Concerns have been raised that lack of coordination and information sharing among various institutions is a weakness that affects IP enforcement in Kenya.[54] Information sharing can be facilitated by replacing the current divergence of powers with a convergence situation, particularly by including provisions in the Anti-Counterfeit Act to enable all relevant institutions to work closely with each other, thus pooling the available technical and human resources in a bid to combat counterfeiting.

The frameworks in South Africa

The noted weaknesses in the Kenyan act warrant a comparison with the South African regime, in view of the fact that the Kenyan government enacted the legislation after consulting with other jurisdictions such as the USA, Canada, South Africa and the UK.[55] Out of these countries that were consulted by

52 NG Thoithi and FA Okalebo "Country case study: Kenya" in *FIP Global Pharmacy Workforce Report* (2009) 49 at 51.

53 The Standards Act, chap 496, sec 4(1)(i).

54 International Chamber of Commerce "Promoting and protecting intellectual property in Kenya", available at: <http://www.iccwbo.org/Data/Documents/Bascap/International-engagement-and-advocacy/Country-Initiatives/Kenya/Value-of-IP-in-Kenya/> (last accessed 12 November 2013).

55 C Mputhia "Anti-counterfeits law sparks debate in industry" (21 September 2009) *Business Daily*, available at: <http://www.businessdailyafrica.com/-/539444/660914/-/rypuya/-/index.html> (last accessed 10 October 2013).

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Kenya, South Africa is chosen for comparative purposes due to its efforts to utilize its legal regime, together with the involvement of public bodies that have developed codes of ethics with a view to ensuring the quality and safety of medicines for the purposes of protecting public health interests. The South African Counterfeit Goods Act (CGA)[56] also has similarities with the Kenyan act, particularly in its definition of counterfeiting. The various provisions of the CGA have been interpreted by the Supreme Court of Appeal in order to provide clarity on the scope and purpose of the legislation in relation to counterfeit goods generally, while the Kenyan legislation has been judicially tested in its protection of public health interests. It is therefore worth considering how Kenya can learn from South Africa's considerable experience in streamlining the scope and application of the counterfeiting legislation. South Africa can equally learn lessons from the Kenyan court's pronouncement on the application of counterfeiting legislation to public health.

South Africa has used a combination of legislation and codes of ethics to ensure the safety of medicines. Standard operating procedures and audits by manufacturers, distributors and health care providers have been used in a bid to ensure quality of medicines in South Africa.[57]

The Counterfeit Goods Act

Before the enactment of the CGA, counterfeiting was dealt with by the Merchandise Marks Act,[58] the Copyright Act[59] and the Trademarks Act.[60] There were concerns that these laws "lacked appropriate and effective enforcement mechanisms, procedures and penalties for combating counterfeiting".[61] Section 185(1) of the Companies Act[62] established the Companies and IP Commission, which, under the national IP policy,[63] is responsible for the enforcement of IP. According to the information posted on the commission's website, it is the custodian of the CGA and is jointly responsible with the South African Revenue Services (SARS) and South African Police Services (SAPS) for enforcing the act.[64]

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56 Act No 37 of 1997.

57 A Patel, P Norris, R Gauld et al "Drug quality in South Africa: Perceptions of key players involved in medicines distribution" (2009) 22/5 *International Journal of Health Care Quality Assurance* 547.

58 Act 17 of 1941.

59 Act 98 of 1978.

60 Act 194 of 1993.

61 M Khader "South Africa" in *The World Trademark Review: Anti-Counterfeiting 2013 – A Global Guide* (2013, Globe Business Publishing) 188 at 188.

62 Companies Act, 2008.

63 Department of Trade and Industry "Draft national policy on intellectual property 2013" (notice 918 of 2013), chap 15 at 43.

64 "Complaints in terms of the Counterfeit Goods Act (No 37 of 1997)", available at: <http://www.cipc.co.za/index.php/trade-marks-patents-designs-copyright/enforcement/how-lodge-complaint/> (last accessed 26 November 2015).

One of the commission's objectives under section 186(1)(c) of the Companies Act, 2008 is to promote education and awareness of company and IP laws. Section 188(2)(d) equally requires the commission to promote public awareness of company and IP law matters by reviewing legislation and public regulations and reporting to the minister responsible. Interestingly, section 3(1) of the CGA defines the minister as the minister of trade and industry and an inspector is the recipient of complaints. There seems to be a disconnect here, because the CGA does not seem to provide for the role of the newly established commission.

The CGA defines counterfeiting as: "… without the authority of the owner of any intellectual property right subsisting in the Republic in respect of protected goods, the manufacturing, producing or making, whether in the Republic or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are substantially identical copies of the protected goods".[65]

This definition has also taken a substantive expansion approach as it does not limit itself to trademarks in terms of TRIPS. This will need to be reviewed if the proposal in the draft national IP policy, that generic medicines should not be confused with counterfeit medicines, is to yield tangible fruits. The draft policy specifically recommends that "law enforcement agencies in particular SARS, should not confiscate [generic medicines] when in transit".[66] The policy also recommends education and awareness "among law enforcement agencies that generics are not counterfeit medicines".[67] These recommendations are well-intended but the current definition of counterfeit will make them difficult to implement. The definition should be amended explicitly to exclude the broad reference to IPRs, which implies the inclusion of patents, thereby impacting negatively on generics. The current definition allows law enforcement agencies to confiscate generics, as they fall within the scope of the broad definition.

Section 3(1) provides that the holder of an IP right, or the representative or attorney of such a right holder, can lodge a complaint with SAPS or with an inspector appointed as such under section 22 of the act.[68] If the police or inspector is satisfied that an offence has been committed they can obtain a warrant, from the High Court or a magistrates' court, to seize the goods under section 6. Such warrants are issued in chambers on any day of the week.[69]

The Supreme Court of Appeal ruled in the case of *Commissioner, South African Revenue Service and Others v Moresport (Pty) Ltd and Others*[70] that, at this stage,

65 Sec 1(1)(iv)
66 Chap 1 at 13.
67 Ibid.
68 Sec 22.
69 CGA, sec 6(3).
70 2009 (6) SA 220 (SCA).

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"the judge or magistrate is not required to adjudicate on the dispute on whether the goods are indeed counterfeit or not but merely to make a decision on whether there are reasonable grounds for believing that an act of dealing in counterfeit goods has taken or is taking or is likely to take place".[71]

It is also important to note that inspectors are authorized under section 5(2), during the day and without a warrant, to enter any premises (except private dwellings, which are exempt under subsection 3) or vehicle to search, seize and detain suspected counterfeit goods. In such situations, where an inspector has acted on his or her own initiative, section 5(4) provides that such action must be confirmed by a judge or magistrate with jurisdiction; otherwise it ceases to have legal validity. These wide-ranging powers can be useful for averting the release of counterfeit medicines into the main supply chain. Section 10(2)(a) specifically provides that counterfeit goods "may not be released into the channels of commerce upon the mere removal of the subject matter of the intellectual property right that was unlawfully applied to those goods".

The powers in section 5(4) were exercised by inspectors who stumbled on additional counterfeit goods in the case of *Minister of Trade and Industry and Another v El Enterprises and Another*.[72] The inspector in this case obtained a warrant authorizing him to enter and search the premises of the respondents and seize "screen printing plates, boxes, empty or filled that imitated the registered [OMO] trademarks".[73] While searching the premises of the respondents in accordance with the warrant, the inspector found images, positives and screen prints bearing SUNLIGHT and RAJAH trademarks that, according to information furnished by the trademark owners, the respondents were not authorized to produce.[74] Clearly it may not be practical in such circumstances to obtain a warrant in respect of additional discoveries made in the course of the search before seizing them, as the goods may be removed from the scene and moved to an unknown location while the inspector is still attempting to obtain a warrant.

The following justification for proceeding to seize the goods without a warrant was clearly explained by the inspector in his affidavit, which was filed on appeal since the lower court declined to grant the warrant after the goods had been seized, due to confusion regarding the correct procedure required under section 5(4):

> "I could not leave the premises to approach a magistrate for a warrant because I was the only inspector available at the scene and there were no additional inspectors to secure the goods. It was Friday afternoon at about 16:30 and the chances were slim that a magistrate would still have been available at that hour. I am of the opinion that I had sufficient evidence to proceed

71 Id, para 9.
72 2011 (1) SA 581 (SCA).
73 Id, para 4.
74 Id, para 5.

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> without a warrant and that a warrant would have been granted by a magistrate in the circumstances. I am also of the opinion that the delay that would have ensued by me first obtaining the warrant would have defeated the object and purpose of the seizure, and removal and detention of the evidence."[75]

The contentious issue for the court's determination was that the inspector filed the application under section 5(4), within the required period of ten days, seeking the court's confirmation of his action of seizing and detaining the goods without a warrant, but that the application was served on the respondent suspect after the expiry of the ten day period. Consequently, the respondent argued that such delay implied that the inspector had failed to file the application within the prescribed period. This argument was upheld by the court below. On appeal, it was held "that the nature and purpose of search and seizure in terms of the Act demand that no notice be given. Notice is likely to defeat the purpose of the warrant".[76] The appeal was therefore allowed.

A complainant can bring criminal charges under the act against a suspect for dealing in counterfeit goods as a primary charge, but rights holders are also encouraged to consider additional criminal charges that may relate to non-compliance with national standards, for instance under the National Regulator for Compulsory Specifications Act.[77]

The Supreme Court of Appeal held in the case of *Cadac (Pty) Ltd v Weber-Stephen Products Co and Others*[78] that the CGA is aimed at trademark and copyright infringements of a criminal nature, and rights holders may not invoke its provisions against alleged infringers in order to settle what is in fact a bona fide dispute about the boundaries of rights, which should be litigated in conventional litigation under the Trademarks and Copyright Acts.[79] Justice Harms handed down this judgment, with which the other presiding justices of appeal concurred. The judgment raises two pertinent questions. First is the approach proposed by the court in line with South Africa's obligations under article 61 of TRIPS, which requires "criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale"? Secondly, if infringement of a criminal nature should be punished with the aim of protecting the public, is there any rationale for drawing the suggested line between criminal and civil proceedings, particularly when the matter relates to wilful trademark counterfeiting on a commercial scale?

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75 Id, para 6.
76 Id, para 12.
77 Act No 5 of 2008; see also Khader "South Africa", above at note 61 at 191.
78 2011 (3) SA 570 (SCA).
79 Id, para 6.

Interestingly, Harms had previously critically analysed, elsewhere,[80] the rationale and effectiveness of enforcing IPRs by means of criminal sanctions. His views are useful in addressing these questions. He succinctly observed: "[c]riminal law, in general, protects private rights against infringement if there is a public policy element involved. A typical example is theft. Likewise, wider public interests than the mere protection of private rights are at stake in the case of counterfeiting".[81] One of the public policy elements that he mentions is public health and safety. In his view, criminal enforcement goes hand in hand with civil enforcement. His reasoning is that these two types of enforcement "are not in competition but the former is there to shore up the latter. It should be the fallback, not the prime matter. But the scale of counterfeiting in a particular jurisdiction may require more emphasis on criminal enforcement".[82]

In answer to the first question, the approach proposed by the court is not in line with the requirements of article 61 of TRIPS. It may however be assumed that perhaps the court did not pay attention to this article when handing down the judgment. This means that, in future, South African courts will have to consider entertaining disputes about the boundaries of IPRs under the CGA, particularly if they are related to wilful counterfeiting on a commercial scale. It is also doubtful if the courts will turn away parties who bring matters related to wilful counterfeiting on a commercial scale (as envisaged by article 61 of TRIPS) under the CGA, since their nature is essentially criminal. This conclusion is based on Harms's seminal analysis, noted above,[83] and his additional observation that "legislatures, the prosecution and courts have to prioritize their work [and] IP crimes do not, as a rule, rate high especially in high-crime communities".[84] This statement should be understood in the context of developing countries, where IP enforcement is not at the top of the agenda as most countries have other priorities. In South Africa, primary concerns are the eradication of poverty, illiteracy, unemployment and the high rate of violent crime.[85]

Section 17(1) of the CGA entitles any person who suffers damage or loss, caused by the wrongful seizure, removal or detention of goods that are suspected to be counterfeit, to claim compensation against the complainant for that damage or loss.

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80 WIPO Advisory Committee on Enforcement "The enforcement of intellectual property rights by means of criminal sanctions: An assessment" (prepared by L Harms, fourth session Geneva, 1 and 2 November 2007).

81 Id, para 16.

82 Id, para 186.

83 Ibid.

84 Id, para 148.

85 DR Nicholson "Intellectual property: Benefit or burden for Africa?" (2006) 32 *IFLA Journal* 310.

Institutional frameworks that ensure compliance with standards

The statutory body that deals with applications for the registration of medicines and medical devices is the Medicines Control Council (MCC), which was established under the Medicines and Related Substances Act[86] (the Medicines Act). The MCC ensures the evaluation of the efficacy, safety and quality of medicines before they are registered and supplied in South Africa.

Section 18C of the Medicines Act empowers the minister, after consultation with the pharmaceutical industry, to make regulations regarding the marketing of health products. Pursuant to this section, a code of practice has been developed with a view to ensuring the ethical promotion of health products and the provision of affordable and quality healthcare for all South Africans.[87] The health products trade associations have adopted the code and this signifies "their commitment to the marketing of health products to healthcare professionals and the public … in a responsible, ethical and professional manner, based on practical and scientifically validated information".[88] Such a commitment to ethical practice is important for combating trade in counterfeits. Clause 2.3.2 of the code provides that "the Code should not be construed to be in conflict with any existing law applicable to the marketing of Medicine". The clause specifies the Trademarks Act as one such law.

Apart from the MCC, the public bodies discussed above under the legal frameworks are worth noting for their direct involvement in combating trade in counterfeit goods. SAPS and SARS play important roles since the inspectors, for the purposes of the CGA, are appointed from these two bodies. It is worth noting that the minister of trade and industry has the power to designate any specified class or category of persons to be inspectors for the purposes of the CGA.[89] This provision could be used to involve as inspectors public bodies that are responsible for setting standards for medicines. Involving such bodies can ensure that counterfeit medicines that can have adverse consequences in public health are not released into the supply chain. As mentioned already, the CGA will have to be amended to accommodate the newly created commission, which is now the custodian of the legislation alongside SARS and SAPS.

Comparison between the Kenyan and South African frameworks

The South African anti-counterfeiting legislation is very similar to that of Kenya. For example, the definition of counterfeiting in section 1(1)(iv) of the CGA is similar to section 2(a)–(c) of the Kenyan act, subject to two exceptions. First, the Kenyan definition of counterfeiting extends counterfeiting to activities regarding IPRs that subsist both in the country and elsewhere, thus

86 Act 101 of 1965.

87 South African Code of Practice for the Marketing of Health Products (October 2010), clause 2.1.

88 Ibid.

89 CGA, sec 22(1).

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making it possible for holders of trademarks that may not necessarily qualify for protection under the Trademarks Act to benefit from the anti-counterfeit legislation. The South African definition limits the scope of IPRs to those subsisting in the country and this includes well-known trademarks, which are protected under section 35 of the Trademarks Act. As mentioned earlier, this broad definition was recently amended through the 2014 amendment bill, which deleted the word "elsewhere", thus restricting counterfeiting to Kenya. Secondly, Kenya's legislation includes a paragraph that specifically refers to medicines, together with a proviso (to section 2d) that nothing in the paragraph shall derogate from the provisions of the Industrial Property Act. This proviso can be taken as having been intended to protect parallel importers. However, as noted in *PAO*, there is a possibility of this provision criminalizing the parallel importation of generic drugs as well.

Considering the similarities between both countries' legal frameworks, the comparison in this section of the article is intended to highlight lessons that the two countries could learn from each other, as well as how these lessons can improve the ongoing developments in the EAC that are discussed in the next part of this article. The three South African cases in which the Supreme Court of Appeal provided clarity on the scope of the CGA and the correct procedures to be followed in implementing the act can provide clear lessons for Kenya. First, the procedures that need to be followed under the act should be clarified, since they seem rather obscure. For instance, it is evidently overwhelming for the office of the ACA executive director to handle all complaints (except those related to imported goods, which are dealt with by the commissioner of the Kenya Revenue Authority) and make decisions on them within the prescribed period. Notably, inspectors can only exercise their powers under section 23(1) after the executive director's office has established that the goods are prima facie counterfeit. In this regard, Kenya can again learn lessons from the more expeditious procedure used in South Africa, where complaints are lodged directly with inspectors.

Secondly, it would also be useful if the already established public institutions were directly involved in combating trade in counterfeits in Kenya, as in South Africa, instead of channelling almost all cases of counterfeiting to ACA because the Kenyan act does not provide clearly for the direct involvement of the existing public bodies in this endeavour. This is evident from the fact that complaints cannot be made directly to the inspectors. A look at the calibre of the people designated as inspectors[90] shows that they are qualified to deal with complaints directly. For instance, with regard to medicines, public health inspectors and inspectors appointed under the Standards Act, the Food, Drugs and Chemical Substances Act, and the Pharmacy and Poisons Act are designated as inspectors, yet they can only exercise their powers after the executive director's office has established that the goods

90 See sec 22(3).

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are prima facie counterfeit! In its survey, WHO established that "information is not shared with other NMRAs [National Medicines Regulatory Authorities] and other enforcers within the countr[ies]".[91] It thus recommended that "specific legislation be developed that empowers NMRAs and criminalizes counterfeit medical products".[92] Involving the PPB would meet this requirement, since the Kenyan legislation already criminalizes counterfeiting.

South Africa can learn lessons from Kenya in two respects. First, considering that the South African anti-counterfeiting legislation makes no reference to counterfeit medicines, it can be argued that, by default, such medicines are treated as any other goods under the act. It thus follows that the concerns raised in *PAO* are relevant to South Africa as well. A clear provision should be created to remove generic medicines from the ambit of the CGA. Secondly, the definition of counterfeiting that both countries have used follows a substantive expansion approach, which is problematic and should be reviewed to bring it in line with TRIPS.

CURRENT TRENDS IN THE EAST AFRICAN COMMUNITY

The draft EAC policy on anti-counterfeiting, anti-piracy and other IPR violations [93] has imposed a substantive expansion approach in other partner states such as Rwanda, Burundi and Tanzania. As noted earlier, Kenya already entrenched this approach in its anti-counterfeit legislation and the pending Ugandan bill has adopted a similar approach.

The policy identified a number of factors that contribute to widespread counterfeiting, including a lack of effective legislation and enforcement mechanisms.[94] It lists pharmaceuticals among the counterfeited products in the region. According to the policy, the rationale behind formulating specific legislation, targeting counterfeiting, is to apply stiff penalties that can make counterfeiting unattractive as a business.[95]

Whereas the policy's objectives are commendable in so far as they aim to create a sound legal regime within the EAC, two of the objectives are evidently problematic in the context of counterfeit medicines, particularly given the current trend of moving towards a substantive expansion of the concept of counterfeiting in the region. The first such objective is to strengthen border measures in order to impound and destroy counterfeit products. This implies that, so long as the law emanating from this policy allows genuine generic medicines to be confused with counterfeits, genuine generics will never reach their destination. The second objective is to "create a conducive

91 WHO "Report of the situation of counterfeit medicines based on data collection tool: WHO regions for Africa and Eastern Mediterranean" WHO/ACM/3, 2010 at 10. Two EAC member countries, Tanzania and Uganda, participated in the survey.

92 Ibid.

93 Draft 14 December 2009.

94 Id at 10.

95 Id at 15.

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investment climate in the region free of unfair competition practices embodied in counterfeiting and piracy".[96] Considering that unfair competition may not necessarily be unlawful, the policy is likely to render the production of generic medicines unfair, thus adversely affecting access to medicines. The focus should rather be on unlawful competition.

The policy specifically recommends that partner countries adopt the definition of counterfeit contained in the South African CGA, which is considered to be brief, concise and inclusive.[97] As already noted, the South African definition is flawed because it adopts the substantive expansion approach, which is not in line with TRIPS.

These policy recommendations have already influenced the draft bill, which was considered by the 28th council meeting in November 2013.[98] Section 3(1) defines counterfeiting as:

> (a) the manufacturing, producing or making, packaging, repackaging and labeling whether in the Community or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are substantially identical copies of the protected goods without the authority of the Owner of any Intellectual Property Right subsisting in the relevant Partner State in respect of Protected Goods;
> (b) the manufacturing, producing or making or applying to goods, whether in the Community or elsewhere, the subject matter of that Intellectual Property Right, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the Protected Goods of the said Owner or any goods manufactured, produced or made under his licence without the authority of the Owner of any Intellectual Property Right subsisting in the relevant Partner State in respect of the Protected Goods."

Reference to IPR in the broad sense is a substantive expansion, which is not aligned with TRIPS. This reflects the influence of the South African and Kenyan approaches discussed above. The definition of IPRs in the same section is limited however to trademarks, copyright and related rights, as well as plant breeders' rights. Although the narrow definition excludes patents from the realm of IPRs, the broad definition of counterfeiting remains problematic. Musungu also observes that, so long as the definition focuses on the similarity of "goods" and not signs, which are usually protected through trademarks, generic companies can still be found liable for counterfeiting if, as required for safety reasons, they use an identical copy of the chemical composition

96 Id at 17.
97 Id, para 4.1.5.
98 The available version at the time of writing this article was the EAC Anti-Counterfeit Bill, 2011, draft 25 October 2011.

even without imitating the trademark.[99] The concerns raised by the court in Kenya in *PAO* should be instructive in this regard.

It is also important to note that the definition leads to inconsistency with legislation that is already in place in some EAC countries. In the case of Uganda, the Industrial Property Act, 2013 includes substantial TIRPS flexibilities[100] and Kenya's Industrial Property Act of 2001 also contains such flexibilities.[101] The actual implementation of these flexibilities depends on how the regional counterfeit legislation is implemented and commentators have correctly observed that these national laws are likely to "run into conflict that would unnecessarily delay the access to generics".[102]

These concerns have been echoed by the East African Health Platform, which suggested that the definition be limited to "wilful infringement of trademarks and copyright only".[103] The platform also finds problematic the recent proposal by the EAC's sectoral council on legal and judicial affairs[104] that the bill be co-ordinated at the regional level by the EAC competition authority. It argues that article 41.5 of TRIPS does not oblige member states to create a special judicial structure or skew resource allocation towards IP enforcement. Consequently, additional measures proposed in the bill must be based on a compelling case. According to the platform, the EAC is using tax resources drawn from a largely poor population for the purposes of promoting TRIPS-plus measures in the region and this raises "significant policy and political questions, which the policy does not consider".[105]

The procedure for lodging complaints mirrors the Kenyan approach. Section 18(1) of the EAC bill provides that complaints should be lodged with the executive director of the national anti-counterfeiting authority in each partner state. Once the executive director is satisfied, as required under section 19, that an act of dealing in counterfeit goods has taken place or is likely to take place then he can exercise his powers after a warrant has been issued under section 21(1). Inspectors only act once warrants have been issued. Although section 20(2) allows inspectors to enter premises or vehicles without

99 Musungu "The potential impact", above at note 2 at 12–13.

100 The act was passed on 22 August 2013 and assented to on 6 January 2014. Sec 8(3)(f) excludes pharmaceutical inventions from protection until 1 January 2016.

101 Act No 3 of 2001. Sec 26(a) excludes products of biotechnological processes from protection.

102 von Braun and Munyi "New enforcement mechanisms", above at note 14 at 248.

103 East African Health Platform "Draft position paper on the impact of the draft EAC Anti-Counterfeit Bill 2013 on Access to Essential Medicines in East Africa", available at: <http://www.eahp.or.tz/uploads/EAHP_POSITION_PAPER_ON_THE_IMPACT_OF_THE_DRAFT_EAC_ANTI_COUNTERFEIT_BILL_2013_ON_ACCESS_TO_MEDICINES.pdf> (last accessed 17 June 2014).

104 EAC Secretariat "Report of the meeting of experts to finalize the draft anti-counterfeit Bill" (Arusha, 9–13 September 2013), para 2.0.

105 East African Health Platform "Draft position paper", above at note 103 at 3.

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a warrant and seize suspected goods,[106] it is unclear how such powers are to be exercised in relation to those of the executive director.

One positive approach in the EAC bill is that section 10(1) provides for the designation of, inter alia, pharmacy and poisons authorities as inspectors. The inclusion of such authorities can only be useful if the weaknesses noted above are attended to, particularly when dealing with counterfeit medicines. In fact, the Regional Network for Equity in Health in East and Southern Africa (EQUINET) has noted that the anti-counterfeiting laws in eastern and southern African countries are so wide that they obstruct access to medicines. It has provided three key messages that should guide these countries in ensuring that their laws are suitable for protecting public health interests. These messages are:

> "Controlling substandard, falsified medicine calls for special measures and competencies and should be the responsibility of national drug regulatory agencies … In passing anti-counterfeit laws, countries need to define counterfeiting within the limited scope of the TRIPS agreement and separate this from the laws and drug regulatory systems governing substandard and falsified medicines. They should ensure that the definition excludes generic medicines; and preserve their rights to use TRIPS flexibilities … The authority empowered to implement counterfeit law in relation to medicines should be the national drug regulatory authority".[107]

These three messages justify the criticisms against the approach that Kenya, South Africa and the EAC have taken in their anti-counterfeiting legislation. They also inform the discussion in the next part of this article. The first message shows the need to target IP enforcement narrowly and supplement it with the functions of DRAs, which are more qualified to deal with substandard medicines. There is obviously an overlap in these functions since IP enforcement is likely to unearth substandard medicines. The second and third messages show the rationale of the suggestion made below in relation to the Kenyan definition of counterfeit medicines that the function of determining what is counterfeit should be entrusted to the PPB, which should be empowered under anti-counterfeiting legislation to work closely with ACA.

BALANCING THE PROTECTION OF PUBLIC HEALTH INTERESTS AND TRADEMARKS

The public's concern is that medicines that are supplied for use are safe and affordable. This brings two separate issues to light: counterfeit medicines

106 Such acts must be confirmed by a judge or magistrate having jurisdiction, on application of the inspector within seven days after the date when the acts were performed.

107 Center for Health, Human Rights and Development (CEHURD) "Anti-counterfeiting laws and access to essential medicines in East and Southern Africa" (EQUINET, CEHURD, TARSC policy brief 22) (2010, EQUINET) at 1.

and substandard medicines. As indicated in EQUINET's message above, the two issues should not be confused, because substandard medicines may be counterfeit or genuine. Counterfeiting laws should accordingly focus on counterfeit medicines, in view of their direct connection with trademark infringement. However, the approach proposed to deal with counterfeit medicines can be useful in dealing with both types of medicines, since it has been suggested that the "focus of attention should rather be on the detection and removal of poor quality medicines, whether or not they are counterfeit, while at the same time assisting legitimate manufacturers to improve the quality of their pharmaceutical production".[108] A balance can therefore be struck by directly involving the NMRAs in enforcing anti-counterfeit laws. Otherwise there is a danger of using IP enforcement in a manner that is contrary to public health interests.

The need to balance the protection of IP with considerations of public health interests was highlighted in *PAO*, where justice Mumbi observed:

> "The Anti-Counterfeit Act has … 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."[109]

The court's observation is instructive of the need to look at the problem of counterfeiting from a public health perspective, by focusing more on the unsafe nature of the medicines, rather than trademark enforcement. One useful suggestion that has been made in this regard would be to consider "health policy, commercial strategies and regulatory practices and their unintended incentives",[110] which may encourage trade in counterfeit medicines. Consequently, the consideration that states have an obligation to put in place a health system that ensures access to good quality essential medicines would be useful for striking a balance between protecting trademarks and public health interests. This obligation implies that, in the case of counterfeit medicines, "a state must establish a regulatory system to check medicine safety and quality".[111] A close look at the anti-counterfeit laws in Kenya, South Africa

108 JM Caudron, N Ford, M Henkens, C Mace, R Kiddle-Monroe and J Pinel "Substandard medicines in resource-poor settings: A problem that can no longer be ignored" (2008) 13/8 *Tropical Medicine and International Health* 1062 at 1070.

109 *PAO*, para 83.

110 Tremblay "Medicines counterfeiting", above at note 10 at 44.

111 P Hunt and G Backman "Health systems and the right to the highest attainable standard of health" (2008) 10/1 *Health and Human Rights* 81 at 85.

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and the EAC shows that the DRAs are not directly involved in post-regulatory approval quality assurance.

Apart from the Anti-Counterfeit Act, Kenya has an enabling legal framework that needs to be utilized appropriately to ensure the safety and efficacy of medicines. For instance, section 35A(5) of the Pharmacy and Poisons Act empowers the director of the National Drug Quality Control Laboratory, or any member of the laboratory staff who is duly authorized by him, to enter and sample any manufacturing premises with a view to certifying that the method of manufacture approved by the PPB is being followed. The question that arises here is how, in relation to counterfeit goods, these powers could be exercised alongside those of the ACA executive director if both public bodies were to target the same premises with a view to combating the suspected manufacture of counterfeit medicines. It is also worth noting, as evidence provided by Abbott Laboratories shows, that counterfeiters are increasingly using the secondary market where products are purchased from sources other than the original manufacturer.[112] In these circumstances, the codes of ethics that govern manufacturers cannot be guaranteed to have been followed. Such evidence provides the basis for the argument in this article that legislative provisions ensuring manufacturers' compliance with standards should be used strategically to enable regulatory authorities to check compliance by stakeholders in the secondary market as well. This could be done by ensuring that anti-counterfeiting legislation provides for the direct involvement of such regulatory authorities in checking the quality of suspected counterfeit medicines as a way of subjecting the secondary market to the same compliance requirements. If this approach is not used, then there is a high probability that unsafe medicines, which anti-counterfeiting authorities have satisfied themselves not to be counterfeit, will find their way back into the supply chain, causing harm to the public.

In the case of Kenya, this suggestion can be implemented by replacing the current definition of counterfeit medicines in section 2d of the Anti-Counterfeit Act with a proviso empowering the PPB to check suspected counterfeit medicines for compliance with manufacturing standards, as well as verifying the authenticity or otherwise of the medicines. Such a proviso can effectively create a way by which ACA and the PPB can work closely in combating the influx of counterfeit medicines into the market and ensuring that genuine generic medicines are not treated as counterfeit. The following definition of falsified medical products, proposed by the WHO working group of member states on SSFFC medical products, should be considered in defining counterfeit medicines:

112 "Abbott global citizen report, 2013" at 48, available at: <http://prod2.dam.abbott.com/global/documents/pdfs/abbott-citizenship/global-reports/Abbott_longform_report.pdf> (last accessed 8 December 2015).

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> "[A] falsified medical product gives a false representation of its identity and / or source and / or record keeping for traceability; pretends to have been assessed and approved by the competent regulatory authority, pretending to be a genuine quality product; has an intention to deceive by a fraudulent activity; is falsified for profit motives, *disregarding public health and safety*; and that *disputes concerning patents or trademarks must not be confused with falsification of medical products*."[113]

The emphasized clauses in this definition highlight two important factors that should be considered in balancing the protection of public health interests and of trademarks: regard for public health and safety should be checked and entrusted to the DRAs; and issues concerning trademarks should be dealt with through anti-counterfeit legislation. Reckoning with these factors will provide a clear link between the DRAs and anti-counterfeiting authorities. It will also ensure that anti-counterfeit laws are used to achieve public health goals while also protecting the commercial interests of IP owners.

Corruption has also been identified as contributing to counterfeiting. In Kenya, it is reported that bribing to avoid government regulation of drugs has contributed to the increasing problem of counterfeit goods.[114] Involving regulatory authorities that ensure the safety and standards of medicines, in combating trade in counterfeit medicines, can be useful in detecting medicines that may have been released into the supply chain without regulatory approval due to corruption.

Lack of efficiency on the part of regulatory authorities that are entrusted with monitoring the safety of drugs in South Africa was highlighted by the court in the case of *Treatment Action Campaign and Another v Rath and Others*.[115] In this case, the applicants accused the Rath respondents of selling and/or distributing Vitacor Plus, Epican Forte, Lysin-C Drink Mix and VitaCell (the products) in South Africa without complying with the provisions of the Medicines Act. They also accused the Rath respondents of publishing false and misleading advertisements regarding the efficacy of the products in the treatment and prevention of HIV or AIDS. The applicants' case against the government respondents was that they had failed in their duties to investigate unlawful activities of the Rath respondents properly and to take reasonable measures to prevent them. The court held that the Rath respondents' activities were unlawful and that the government respondents had failed in their duty to stop such unlawful activities because they had failed to use the provisions of the Medicines Act to enter upon the premises where the unlawful activities were being carried out in order to investigate the allegations made against the Rath respondents.

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113 WHO "Report of the working group", above at note 17, para 10 (emphasis added).

114 Kenya Anti-Corruption Authority "Sectoral perspective on corruption in Kenya: The case of the public health care delivery" (February 2010).

115 [2008] 4 ALL SA 360 (C) 13 June 2008.

Protecting public health interests would thus require both countries and the EAC to drop TRIPS-plus provisions from their anti-counterfeit laws and empower DRAs by involving them directly in enforcing such laws. However the mandate of the DRAs must be clearly defined and limited to issues of sub-standard counterfeit medicines.

CONCLUSION

This article has analysed the legal and institutional frameworks that Kenya and South Africa are using in a bid to combat counterfeiting and the extent to which those frameworks have influenced current developments in the EAC, particularly with regard to the enactment of TRIPS-plus measures, which threaten the generic industry. It has also considered the extent to which these frameworks are capable of protecting public health interests. It is hoped that, as the EAC grapples with developing the pending anti-counterfeiting bill and the WHO member state mechanism attempts to achieve the goal of protecting public health, the following lessons from Kenya and South Africa will be helpful.

First, TRIPS-plus provisions should be excluded from anti-counterfeit laws and the definition of counterfeit goods should not be so broad as to include generic medicines. Secondly, the procedure of dealing with complaints related to counterfeiting should be more expeditious. Complaints in Kenya and the EAC should be made directly to the inspectors. Thirdly, Kenya and the EAC should involve established public bodies directly in their efforts to combat trade in counterfeits. Currently, too many responsibilities are being entrusted to the executive directors of the institutions in EAC partner states. Finally, the designation of inspectors under section 22 of Kenya's anti-counterfeit legislation and section 10(1) of the EAC bill should be made as flexible as the equivalent provision in South Africa's legislation.

One major limitation of this article is that not much literature is available on the extent to which standard setting regulatory bodies in both countries and in EAC partner countries are involved in combating trade in counterfeit medicines. However, what is clear from the discussions in this article is that public health interests need to be taken into consideration in using anti-counterfeit legislation with a view to protecting consumers against the influx of counterfeit medicines.