

**SAFEGUARDING ACCESS TO ESSENTIAL GENERIC MEDICINES IN KENYA'S  
ANTI-COUNTERFEIT ACT: IMPLEMENTING *P.A.O & 2 OTHERS V AG* DECISION**

**SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT OF THE  
DEGREE**

**LLM (HUMAN RIGHTS AND DEMOCRATISATION IN AFRICA)**

**BY**

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**OCTOBER 2012**

## Declaration

I, **Paul Omondi Ogendi**, hereby declare that the dissertation is an original work and has never been presented to any other institution. I also declare that all secondary information used has been duly acknowledged in this dissertation.

Signed.....

Date.....

**Supervisor: Professor CK Agomo (University of Lagos, Faculty of Law)**

Signature.....

Date.....

## Acknowledgements

I acknowledge the Centre for Human Rights University of Pretoria for the unique opportunity to enrich my knowledge and experience in the field of human rights and democratization in Africa during the academic year 2012.

I am highly indebted to the LLM HRDA class of 2012, lecturers and tutors. Thank you for your love and support throughout the journey.

Immense gratitude to Professor CK Agomo for supervising my work; your guidance was invaluable. I also extend immense appreciation to University of Lagos' Professor Ayo Atsenuwa and Dr (Mrs) Oyewunmi Joke, and University of KwaZulu Natal's Professor Yousuf Vawda, my classmate Freda Apiyo and my colleague Primah Kwagala for reading through my drafts and commenting on them.

Special thanks to the University of Lagos and the entire teaching and student fraternity for hosting my second semester and providing an appropriate academic environment to conduct this research.

## **Dedication**

I dedicate this work to the global access to essential medicines advocates.

## List of abbreviations

ALP	-	AIDS Law Project
ACA	-	Anti-Counterfeit Act
ARV	-	Antiretroviral
AU	-	African Union
AIDS	-	Acquired Immuno-Deficiency Syndrome
CEDAW	-	Convention on the Elimination of All forms of Discrimination Against Women
CESCR	-	Committee on Economic Social and Cultural Rights
COMESA	-	Common Market for Eastern and Southern Africa
CRC	-	Convention on the Rights of the Child
CRPD	-	Convention on the Rights of Persons with Disabilities
EAC	-	East African Community
GATT	-	General Agreement on Trade and Tariffs
HAPCA	-	HIV and AIDS Prevention and Control Act
HIV	-	Human Immuno-Deficiency Virus
ICDRA	-	International Conference of Drug Regulatory Authorities
ICESCR	-	International Covenant on Economic, Social and Cultural Rights
IGAD	-	Intergovernmental Authority on Development
IMPACT	-	International Medical Products Anti-Counterfeiting Taskforce
IPRs	-	Intellectual Property Rights
KNASP	-	Kenya National AIDS Strategic Plan
LDC	-	Least Developed Country
MDG	-	Millennium Development Goal
NMRA	-	National Medicines Regulatory Authority
PBR	-	Plant Breeders' Rights
PMTCT	-	Prevention of Mother-To-Child Transmission
PPB	-	Pharmacy and Poisons Board
TRIPS	-	Trade Related Aspects of International Property Rights
UN	-	United Nations
UDHR	-	Universal Declaration of Human Rights
WHO	-	World Health Organization
WTO	-	World Trade Organization

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# Chapter One

## 1. Introduction

### 1.1 Background

One key outcome of the Uruguay round of negotiations was the adoption of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement<sup>1</sup>. The TRIPS Agreement is a multilateral treaty amongst the World Trade Organization (WTO) members providing for, amongst other things, the minimum standards for intellectual property rights (IPRs) protection and enforcement. The standards under the TRIPS Agreement, however, are, comparatively, higher than most IPRs international instruments. It generally applies equally, with some flexibilities for developing countries, to both the developed and developing countries' whose previous commitment on IPRs protection was either 'non-existence or at best unequivocal'.<sup>2</sup> The general obligation under the TRIPS Agreement is to enact legislations or/and other measures to provide for national protection of IPRs.<sup>3</sup> Unlike other World Intellectual Property Organisation (WIPO) treaties,<sup>4</sup> the violation of the TRIPS Agreement, in most cases, attracts economic sanctions at the WTO through the Dispute Settlement Unit (DSU).<sup>5</sup> In this manner, the TRIPS Agreement has not only succeeded in linking the IPRs protection to the world trading system but it has also created 'a new and robust' international and national enforcement opportunities in WTO member countries.<sup>6</sup>

Prior to the enactment of the TRIPS Agreement, both developed and developing countries had divergent competing interests. Developed nations, on one hand, were mainly

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<sup>1</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The legal texts: The results of the Uruguay round of multilateral trade negotiations 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994). According to Marett, the negotiations on IP in the Uruguay Round were particularly difficult and even now there is some feeling not exclusively confined to developing countries, that the provisions were forced through by the economic might of the United States rather than agreed by general consensus. See, P Marett *Marett: Intellectual property law* (1996) 235.

<sup>2</sup> LR Helfer 'Human rights and intellectual property: conflict or co-existence?' (2003) 5 *Minnesota Intellectual Property Review* 53.

<sup>3</sup> Article 1(1) of the TRIPS Agreement provides that '...Members shall be free to determine the appropriate method of implementing the provision of this Agreement within their own legal system and practice.' For a discussion on developing countries implementation of the TRIPS Agreement, see also G Gidhini 'On the impact of TRIPS on "least developed countries": A tale of double standards?' (2011) 1 *Queen Mary Journal of Intellectual Property* 73-79.

<sup>4</sup> Most notably are the Paris and Berne Conventions.

<sup>5</sup> JH Reichman *The TRIPS Agreement comes of age: conflicts or cooperation with the developing countries* (2000) quoted in Helfer above.

<sup>6</sup> LR Helfer 'Towards a human rights framework for intellectual property' (2007) 40 *U.C. Davis Law Review* 973. Prior to the TRIPS Agreement, IPRs disputes between countries could only be addressed at the International Court of Justice (ICJ).



interested in the enforcement of IPRs throughout the world.<sup>7</sup> Pharmaceutical industries, during the negotiations, were particularly interested in the global extension of their IPRs and, therefore, lobbied hard in this respect.<sup>8</sup> Developing countries, on their part, were pre-occupied with fixing their ailing public health systems, and to some extent deriving economic and technological advantages in the new system.<sup>9</sup> India, for example, had continued to experience high medicines prices and, therefore, wanted out of the TRIPS Agreement negotiations a system that would allow for 'more access to technology that had been locked up by means of patent'.<sup>10</sup>

From the foregoing, arguably, the TRIPS Agreement may have failed to fully satisfy all the expectations of both developed and developing countries. Developing countries, particularly, have faced strong opposition in the WTO TRIPS Agreement framework in their attempt to exploit IPRs.<sup>11</sup> In 2001, the Doha Declaration on the TRIPS Agreement and Public Health was negotiated and adopted and it clarified that the TRIPS Agreement 'does not and should not' inhibit developing countries from intervening to protect their public health systems including during emergencies such as HIV and AIDS, tuberculosis and malaria.<sup>12</sup> This happened after it emerged that the TRIPS Agreement was having a significant 'human rights implications, including [in] public health, education, food and agriculture, privacy, and freedom of expression'.<sup>13</sup>

On the part of developed countries, the failure of the TRIPS Agreement to put an end to piracy and counterfeiting was a big disappointment.<sup>14</sup> In reaction, developed countries accused developing countries for not sufficiently enforcing IPRs. They also complained about allocation

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<sup>7</sup> P Drahos & H Smith 'The universality of intellectual property rights: Origins and development' (1998) 8 – 10, [www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/drahos.pdf](http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/drahos.pdf) (accessed 30 September 2012).

<sup>8</sup> Commission on Intellectual Property Rights (2002): Integrating Intellectual Property Rights and Development Policy (2002) 29 London: Commission on Intellectual Property Rights, [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm) (accessed 21 October 2012).

<sup>9</sup> As above.

<sup>10</sup> Drahos & Smith (n 7 above), 8-9.

<sup>11</sup> Illustratively, South Africa sought to streamline its access to medicines law in line with their new National Drug Policy. As a consequence, the US placed South Africa on the Special 301 watch list for not providing adequate and effective IPRs protection. Similarly, a group of 39 pharmaceutical companies went to court to challenge the decision. The measures were reversed after worldwide condemnation. See, 'International petition campaign launched' *Doctors without Borders* 12 March 2001, <http://www.doctorswithoutborders.org/press/release.cfm?id=662&cat=press-release>.

<sup>12</sup> World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, (Ministerial Conference Fourth Session Doha, 9-14 November 2001, Decision No: WT/MIN(01)/DEC/W/2, 14 November 2001).

<sup>13</sup> Helfer (n 6 above), 973.

<sup>14</sup> A Kur 'International norm-making in the field of intellectual property: A shift towards maximum rules?' (2009) 1 *WIPO Journal* 28.

of resources by developing countries for IPRs enforcement.<sup>15</sup> To fill this enforcement gap, developed countries devised another strategy, outside the TRIPS Agreement framework, which is predominantly characterised by bilateral trade negotiations for more IPRs protection in exchange of more market access concessions.<sup>16</sup> The new strategy appears to be working as evidenced by the proliferation of anti-counterfeiting legislations in developing countries including Africa.<sup>17</sup>

However, the anti-counterfeiting legislations in Africa particularly are more concerning because of adopting TRIPS plus<sup>18</sup> measures in form of unbalanced stronger IPRs enforcement standards including for patents.<sup>19</sup> Concerned about the implications of stronger IPRs protection agenda, developing countries have shifted to other forums including the World Health Organization (WHO), Food and Agriculture Organization (FAO) and the Conferences on Convention on Bio-Diversity (CBD) to 'seek to roll back IP or at least eschew further expansion of the monopoly privilege they confer'.<sup>20</sup> Africa's importance in the anti-counterfeiting war, arguably, is attributable to the fact that it is both a destination and also a transit route for counterfeit products from China and other countries.<sup>21</sup>

The magnitude of the issues emerging in this conflict has attracted other previously unconcerned actors. For example, the global access to medicines actors who have, amongst other things, expressed reservations against anti-counterfeit legislations in Africa. According to these actors, the anti-counterfeiting legislations, as currently being enacted in Africa, would restrict free transit of generics, impose chilling effects on the medicines trade, and limit flexibilities in intellectual property rules; it would also impede legitimate competition, short change the legal process, and shift the costs of enforcing private civil patent rights to the

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<sup>15</sup> As above.

<sup>16</sup> As above, 33.

<sup>17</sup> United Nations Development Programme (UNDP) 'Anti-counterfeit laws and public health: What to look out for' UNDP Discussion paper (2012) 7, [www.undp.org/content/undp/en/home/librarypage/hiv-aids/discussion-paper---anti-counterfeit-laws-and-public-health---wha/](http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/discussion-paper---anti-counterfeit-laws-and-public-health---wha/) (accessed 6 September 2012).

<sup>18</sup> This term is generally used to refer to legislations or agreement that adopts higher protection standards beyond the TRIPS Agreement.

<sup>19</sup> The Kenyan Anti-Counterfeit Act for example establishes the Kenya Anti-Counterfeit Agency and also provides for counterfeiting offences amongst other measures. Punishments are either in form of jail sentences or fines which are calculated in relation to the value of legitimate goods in the market.

<sup>20</sup> As above, 974.

<sup>21</sup> M Haman 'Africa rising to the anti-counterfeiting challenge' (2010) 5 *Journal of Intellectual Property Law and Practice* 345.

public.<sup>22</sup> According to UNDP, the things to look out for in an anti-counterfeit legislation include:<sup>23</sup>

its overbroad definition of 'counterfeit'; its criminalization of all IP infringements, including patents; its granting broad powers to government agencies, especially customs officials, without judicial oversight; its providing for harsh criminal and other penalties; and shifting presumption of evidence.

One of the strategies that have been adopted successfully by global access to medicines actors is public interest litigation. Kenya is a good example of where public interest litigation has produced positive results. In 2009, three persons living positively with HIV brought a petition<sup>24</sup> before the Kenyan High Court challenging the provisions of the Kenya Anti-Counterfeiting Act<sup>25</sup>. In their petition, they argued that the provisions, specifically, sections 2, 32 and 34, of the Anti-Counterfeit Act would restrict access to essential medicines including generics if implemented. Consequently, it would constitute a violation of their constitutional rights to life under Article 26(1), to human dignity under Article 28, and to the highest attainable standard of health under Article 43(1). The High Court, in a landmark judgment, ruled in favour of the petitioners and granted all their prayers.

The victory in this case was, undoubtedly, a major achievement for the global access to medicines advocates but there must be no room for complacency. In implementing the decision, various challenges are expected particularly from trade and investments actors. This will play out in various manners including in trying to negotiate a balance between a strong anti-counterfeit legislation and adequate safeguards for access to essential medicines.<sup>26</sup> In this regard, it will be inevitable to utilise the 'Musungu framework' principles to generate the appropriate amendments to guarantee access to essential medicines.<sup>27</sup> This is particularly so because the option of amending the Anti-Counterfeit Act is more probable than repealing it. Indeed, developing countries should be concerned with international trade in counterfeit and

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<sup>22</sup> C McManis 'The proposed anti-counterfeiting trade agreement (ACTA): Two tales of a treaty' (2009-2010) 46 *Houston Law Review* 1237.

<sup>23</sup> UNDP (n 17 above), 7.

<sup>24</sup> *P.AO & 2 others v Attorney General & Another* (2012) eKLR, [http://www.kenyalaw.org/CaseSearch/view\\_preview1.php?link=60368366085611182278427](http://www.kenyalaw.org/CaseSearch/view_preview1.php?link=60368366085611182278427) (accessed 20 June 2012). (the *PATRICIA ASERO case* decision).

<sup>25</sup> Cap 13 of 2008 Laws of Kenya.

<sup>26</sup> 'UNAIDS welcomes Kenya High Court judgment on anti-counterfeit law' *UNAIDS press statement* 20 April 2012, <http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2012/april/20120420pskenya/> (accessed 2 October 2012).

<sup>27</sup> See generally, UNDP (n 17 above). Chapter four of this study utilises the 'Musungu framework' to generate a model amendment law for the Anti-Counterfeit Act.

pirated good if not for anything else but because trade in counterfeit and pirated goods also contributes to organised crimes and terrorism.<sup>28</sup>

## 1.2 Statement of the research problem

The High Court of Kenya declared the Anti-Counterfeit Act unconstitutional because of its provisions affecting access to essential medicines including generics. The High Court was particularly concerned with the inadequate provisions under the Anti-Counterfeit Act to safeguard access to essential medicines. Noticing this gap, the presiding Judge recommended a review of the definition of 'counterfeiting' under section 2 of the Anti-Counterfeit Act amongst other measures to sufficiently safeguard access to essential medicines including generics.<sup>29</sup> Thus, the main problem addressed in this study relates to the process and substance of Anti-Counterfeit Act amendment especially with regard to safeguarding access to essential medicines including generics in Kenya.<sup>30</sup>

## 1.3 The main objective of the study

The main objective of the study is to analyse the implementation of the *Patricia Asero* case decision. However, the specific objectives of this study are, namely: to discuss the *Patricia Asero* case decision; to explore the legal and socio-economic imperatives that necessitate the implementation of the decision; and to analyse how the implementation of the decision can be achieved to safeguard access to essential medicines including generics.

## 1.4 Research questions

The main research question addressed in this study is the implementation of the *Patricia Asero* case decision to safeguard access to essential medicines including generics in Kenya. Specifically, this study addresses three questions, namely:

1. What view did the High Court adopt in the *Patricia Asero* case and what are the implications of that decision on access to essential medicines situation in Kenya and beyond?
2. What are the legal and socio-economic imperatives that necessitate the implementation of the *Patricia Asero case* decision to safeguard access to essential medicines in Kenya?

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<sup>28</sup> McManis (n 22 above), 1239.

<sup>29</sup> Para 88 of the decision.

<sup>30</sup> This balance must be achieved without compromising the effectiveness of the anti-counterfeit legislation to combat counterfeit trade in a win-win situation.

3. What tools are needed to engage in the implementation of the *Patricia Asero* case decision and what are the challenges to be experienced by access to essential medicines advocates?

## 1.5 Research methodology

The research was conducted primarily by way of desk-top reviews of available literature. In this study, both primary and secondary data have been consulted to support the analysis and arguments put forward by the author. Primary sources consulted include relevant international treaties and instruments, relevant documents on the subject of this study, local and foreign case laws, and national legislations in Kenya especially on IPRs and human rights. The author in limited cases also interviewed and emailed different resource persons to fill in specific data gaps in the study. Secondary sources consulted include journal articles, books, reports and other electronic sources.

## 1.6 Theoretical framework

Wekesa traces the philosophy on property ownership and categorises them in two schools of thought. These are the deontological or natural rights approach and the consequential or utilitarian approach.<sup>31</sup> This study is concerned with the deontological or natural rights theory which is predominantly associated with Locke who basically 'justified private property ownership based on the premise that every individual should own what he/she produces from the commons'.<sup>32</sup> Thus, the Lockean theory justifies strong IPRs protection to reward innovators and creators.<sup>33</sup> Strong IPRs protection, especially for pharmaceutical products, is inevitable to promote greater innovation and consequently improve human welfare.<sup>34</sup> However, IPRs should not be protected at the expense of human life. Put differently, IPRs protection should not stand on the way of legitimate exploitation of 'lifesaving intellectual goods'.<sup>35</sup> It is unlikely that the

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<sup>31</sup> M Wekesa 'An overview of the intellectual property rights (IPRs) regime in Kenya in M Wekesa & B Sihanya (eds) *Intellectual property rights in Kenya* (2009) 1.

<sup>32</sup> As above, 2. According to Wekesa, the consequential or utilitarianism school holds that IPRs in one's creation is necessary as a means to further development and should only be granted to ensure greater happiness of the larger society. In my view, this theory while plausible I do not subscribe to the fact that IPRs should be granted on the basis of happiness. It should be granted on the basis of hard work and sweat as observed by Locke.

<sup>33</sup> MT Islam 'Protection of public interests through a human rights framework in the TRIPS Agreement: Realities and challenges' (2009) 4 *Journal of Intellectual Property and Practice* 576.

<sup>34</sup> P Agrawal & P Sibaba 'TRIPS and India's pharmaceutical industry' (2001) quoted in Islam above.

<sup>35</sup> R Spitzlinger 'On the idea of owning ideas: Applying Locke's labour appropriation theory to intellectual goods' (2011) 5 *Masaryk University Journal of Law and Technology* 282. 273

Lockean theory regards IPRs protection more superior than saving human lives including through legitimate 'production and dissemination of lifesaving generic medicines'.<sup>36</sup> Accordingly,

[w]hile...intellectual property rights should be protected, where there is a likelihood...that their protection will put in jeopardy fundamental rights such as the right to life of others...they must give way to the fundamental rights of citizens.<sup>37</sup>

In the context of our study, TRIPS plus measures in Kenya's Anti-Counterfeit Act that promotes stronger IPRs protection at the expense of saving lives and therefore should be reversed. If article 61 of the TRIPS Agreement provides for criminal procedures and penalties in at least 'cases of wilful trademark counterfeiting or copyright piracy on a commercial scale', no extension should be entertained if it would result in negative consequences. The definitions adopted by any country should be within the definitions of the TRIPS Agreement to maintain the crucial balance. As such, Article 51 footnote 14 provides:

(a) "counterfeit trademark goods" shall mean 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;

(b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorised by the right holder in the country in the country of production 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 under the law of the country of importation.

Patent linkages in anti-counterfeit laws are not justifiable under the TRIPS Agreement.<sup>38</sup> In practical terms, the protection of patented medicines should not fall under the jurisdiction of anti-counterfeit legislations. The Kenya Anti-Counterfeit Act insofar as it conflates 'counterfeiting' definition to include patent infringement risks criminalising legitimately produced generic medicines.<sup>39</sup> Generic medicines may be produced by way of compulsory licenses,

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<sup>36</sup> As above.

<sup>37</sup> See para 86 of the decision in the *PATRICIA ASERO* case.

<sup>38</sup> Email from YA Vawda, Law Professor at the University of KwaZulu Natal, South Africa, 31 August 2012.

<sup>39</sup> As above.

government use and solar exceptions provisions and should not be illegal in the interest of access.<sup>40</sup>

## 1.8 Literature review

IPRs protection has evolved over a long period of time. Drahos gives a concise account of this evolution by providing a three-stage analysis as follows:<sup>41</sup>

The first period, the territorial period, [was] essentially characterized by absence of international protection. The second [period], the international period, [began] in Europe towards the end of the 19<sup>th</sup> century with some countries agreeing to the formation of the Paris Convention...and...the Berne Convention.... The third period, global period, [had] its origins in the linkage that the United States of America (the U.S.A) made between trade and intellectual property in the 1980s, a linkage which emerged at a multilateral level in the form of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement).

Arguably, a case can be made for the fourth period which is essentially the post-TRIPS Agreement period where the focus for the developed countries have been mainly on bilateral trade and investments agreements negotiations in exchange of market access. For developing countries, the utilisation of other forums, for example, the WHO, to roll-back the ever increasing IPRs monopolies has been on top of their priorities. The ensuing scenario is that 'those who seek to ration access to IP are engaged in an elaborate cat and mouse game with those who seek to expand access';<sup>42</sup> and forum shopping. Thus, when one venue becomes less responsive to a high protectionist agenda, a shift is engineered in search of a 'more hospitable venue' and vice versa.<sup>43</sup>

Due to the fact that the TRIPS Agreement was internationally negotiated, its 'rules v flexibilities' model represents the best compromise between the two sides with competing interests.<sup>44</sup> Sadly, it has largely been ignored especially by developed countries who are busy trying to achieve stronger IPRs enforcements standards. Yet, this balance of public policy objectives of the TRIPS Agreement with the right of developing countries for flexibility should

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<sup>40</sup> Kenyan law and the TRIPS Agreement recognises the right of the government to issue compulsory licenses under certain conditions.

<sup>41</sup> Drahos & Smith (n 7 above), 5.

<sup>42</sup> S Sell 'The global IP upward ratchet, anti-counterfeiting and piracy enforcement efforts: the state of play (2008) 2, [keionline.org/misc-docs/Sell\\_IP\\_Enforcement\\_State\\_of\\_Play-OPs\\_1\\_June\\_2008.pdf](http://keionline.org/misc-docs/Sell_IP_Enforcement_State_of_Play-OPs_1_June_2008.pdf) (accessed 28 August 2012).

<sup>43</sup> As above.

<sup>44</sup> J He 'Developing countries pursuit of an intellectual property law balance under the WTO TRIPS Agreement' (2011) 10 *Chinese Journal of International Law* 830.

be maintained in order to accommodate everyone in the IPRs protection system.<sup>45</sup> The TRIPS Agreement is already an 'upward harmonization' of IPRs protection whose standards should be adequate to guide IPRs protection around the world.<sup>46</sup> Notwithstanding, developed countries continue to exercise their 'political, economic, military, technological and military power' for their domestic gains at the expense of developing countries.<sup>47</sup> Developing countries are often

marginalized in terms of the national interests of great powers, the common interests, values, and prevailing ideology of the international society of States, and in the global power of non-State actors, especially multinational corporation.<sup>48</sup>

The TRIPS Agreement today is being made to work in the interest of developed countries. It is being portrayed to be IPRs protection system whose 'increased levels of protection and enforcement' could be justified on the basis of large scale counterfeiting and piracy.<sup>49</sup> The long term agenda, arguably, is to side-step the TRIPS Agreement and create a more autonomous system with limited incorporation of developing countries' interests.<sup>50</sup> The side-stepping the TRIPS Agreement is shamelessly being based on 'assumptions and statements...not supported by strong evidence'.<sup>51</sup> There exist insufficient evidence to suggest that 'the complexity of the relationship between IP, development, access to medicines and a range of other sectors, including education and agriculture' have been taken into account in this process.<sup>52</sup> The TRIPS Agreement, today, is widely viewed as the 'floor' and presumably, 'only the sky is the limit'.<sup>53</sup> It is not unusual to note 'the common use of the phrase "minimum standards"...[implying] that countries are free to provide additional, more extensive protection'.<sup>54</sup> Below is an account of what is happening:<sup>55</sup>

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<sup>45</sup> P Marett *Marett: Intellectual property law* (1996) 237.

<sup>46</sup> S Sell *Private power, public law: The globalization of intellectual property rights* (2003) 7.

<sup>47</sup> D Fidler 'Introduction: Globalization at the margins: Perspectives on globalization from developing states symposium (1999) 7(1) *Indiana Journal of Global Legal Studies* 2, 3.

<sup>48</sup> As above 3.

<sup>49</sup> B Mercurio 'Beyond the text: The significance of the anti-counterfeiting trade agreement' (2012) 15(2) *Journal of International Economic Law* 363.

<sup>50</sup> W Aldis 'Trends in anti-counterfeiting initiatives: The special cases of "IMPACT" and "ACTA"' (undated) (Thammasat University Thailand). A copy of this document is with the author.

<sup>51</sup> S Musungu 'The potential impact of the proposed East African Community (EAC) Anti-Counterfeiting Policy and Bill on Access to Essential Medicines' (2010) 33 Discussion paper, UNDP BDP HIV Practice, [www.haiafrica.org/index.php?option=com\\_docman&task=doc\\_download&gid=28&Itemid=106](http://www.haiafrica.org/index.php?option=com_docman&task=doc_download&gid=28&Itemid=106) (accessed 30 September 2012).

<sup>52</sup> As above, 34.

<sup>53</sup> HG Ruse-Khan 'Time for a paradigm shift? Exploring maximum standards in international intellectual property protection (2009) 1 *Trade, Law and Development* 58.

<sup>54</sup> As above.

<sup>55</sup> SK Sell 'TRIPS was never enough: Vertical forum shifting, FTAS, ACTA, and TPP' (2011) 18 *Journal of Intellectual Property Law* 448.



Despite the fact that TRIPS advocates triumphantly exclaimed, “we got 95% of what we wanted,” that 5% has always mattered, and 95% was never enough. While many countries believed that they were negotiating a ceiling on intellectual property rules, they quickly discovered that they actually had negotiated a floor. Looking back on the past fifteen years of intellectual property norm setting and governance, critics’ initial objections to TRIPS look almost mild, and I, for one, never imagined that the original TRIPS would look so good.

Previously, human rights and IPRs were regarded as parallel to each other. However, there has been a growing interaction between the two areas of law because of the manifest marginalization of the rights of indigenous people and traditional knowledge generally speaking; and the realization of the consequences of introducing IP as a trade issue under the TRIPS Agreement.<sup>56</sup> One form that this interaction has taken is to focus on the conflict between human rights and intellectual property.<sup>57</sup> Accordingly, the idea is to re-affirm the ‘normative primacy of human rights law over intellectual property law in areas where specific treaty obligations conflict’.<sup>58</sup> Yu contends that to inquire the co-existence or conflict of IPRs and human rights is misleading; and the better approach, therefore, is to alleviate the tension between the human rights and non-human rights aspects of IPRs protection since they are also incorporated in human rights instruments.<sup>59</sup>

The second form is the exploitation of the intersection of human rights and intellectual property as areas of law concerned with defining the appropriate scope of private monopoly power to incentivize future innovation while at the same time guaranteeing public access.<sup>60</sup> This approach emphasizes the compatibility of the two systems ‘although often disagreeing over where to strike the balance between incentives on the one hand and access on the other’.<sup>61</sup> In

The ensuing debate between the human rights and IPRs system trace the problem to patents or poverty.<sup>62</sup> Sell posits that the question of patents versus poverty is not an “either-or” issue’.<sup>63</sup> It appears to her that the focus on the two is unjustifiable because the critical question is to guarantee the flexibilities of countries to pursue different solutions for their different local

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<sup>56</sup> LR Helfer ‘Human rights and intellectual property: Conflict or co-existence’ (2003) 5(1) *Minnesota Intellectual Property Review* 52.

<sup>57</sup> As above, 48.

<sup>58</sup> As above.

<sup>59</sup> PK Yu ‘Reconceptualising intellectual property interests in a human rights framework’ (2007) 40 *U.C. Davis Law Review* 1078.

<sup>60</sup> Helfer (n 56 above) 48.

<sup>61</sup> As above.

<sup>62</sup> SK Sell ‘Trade issues and HIV/AIDS’ (2003) 17 *Emory International Law Review* 933.

<sup>63</sup> As above.

circumstances.<sup>64</sup> Therefore, for example, on the patent question, it is one reason that stronger IPRs protection beyond the standards of TRIPS Agreement is fatal especially for developing countries since it restrict their flexibility and chances to manoeuvre.<sup>65</sup> On the poverty question, without market access for agricultural and textile goods, developing countries will remain poor which will also limit their choices.<sup>66</sup> In this regard, stronger IPRs protection including under anti-counterfeiting legislations, only serves to entrench further the poverty in developing countries.<sup>67</sup> One of the main concerns under Kenya's Anti-Counterfeit Act, for example, is the provision of criminal measures for patent protection despite the fact that it is not an obligation under the TRIPS Agreement; and also that there are civil remedies in Kenya's patent law for patent infringements.

## **1.9 Arrangement of chapters**

This study has five chapters. Chapter one is this introduction containing the background of the study, the statement of the problem, the objective of the study, the research questions, the theoretical framework, the methodology, the literature review and the limitations of the study. Chapter two analyses the *Patricia Asero* case decision. It also tackles the implication of the decision in respect to access to essential medicines. Chapter three explores some legal and socio-economic imperatives that necessitate the implementation of the *Patricia Asero case* decision. It underscores the fact that the majority of Kenyans are poor and therefore dependent on generics. Chapter four discusses the actual implementation of the *Patricia Asero case* decision. It utilises the 'Musungu framework' to generate model amendment law that may act as an advocacy tool. Lastly, Chapter five contains a brief summary of the chapters, the conclusions of the study and its recommendations.

## **1.10 Limitation and the assumption of the study**

The key limitation of the study is that it is biased towards safeguarding access to essential medicines. It assumes that the 'Musungu framework' principles if correctly applied will address the current enforcement problematic elements in Kenya's Anti-Counterfeit Act.

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<sup>64</sup> As above, 934.

<sup>65</sup> As above.

<sup>66</sup> As above, 935.

<sup>67</sup> As above.

## Chapter Two

### 2 Analysis of the *Patricia Asero* case decision

#### 2.1 Introduction

This part predominantly analyses the *Patricia Asero* case decision. In order to undertake the analysis, it describes IPRs protection in Kenya and identifies the essential problem under section of the Anti-Counterfeit Act. By including patent linkage, the Anti-Counterfeit Act ratchets up patent protection, that in turn entrenches monopoly rights. It is feared that, if this is allowed to happen, Kenya and most of its neighbours will experience higher medicines prices. The decision of *Patricia Asero* case is analysed and some of its implications too.

#### 2.2 Overview of Kenya's IPRs legislations

Kenya was a member of the now defunct General Agreement on Tariffs and Trade (GATT 1947). That means that it automatically became a founding member of the World Trade Organization (WTO) and also the TRIPS Agreement on 1 January 1995. The TRIPS Agreement therefore in order to be applicable in Kenya had to be transformed by way of enacting legislations by 31 December 1999.<sup>68</sup> The following are the core instruments enacted by Kenya for IPRs protection: the national Constitution; the Industrial Property Act; the Seeds and Plant varieties Act; the Copyright Act; the Trademark Act; and the Anti-Counterfeit Act.

##### 2.2.1 The Constitution

The Constitution of Kenya was promulgated on 27 August 2010. It is the supreme law of the country. Under the Constitution, IPRs are protected in provisions relating to culture and property rights. Under the former, the state is obliged as part of recognizing culture as the 'foundation of the nation and as the cumulative civilization of the Kenyan people and nation' to 'promote intellectual property rights of the people of Kenya'.<sup>69</sup> In respect to the latter, article 40(5) provides that 'the state shall support, promote and protect the intellectual property rights of the people of Kenya'. Deprivation of property, however, is justifiable in limited circumstances including 'for public purpose or in the public interest'.<sup>70</sup>

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<sup>68</sup> Art 65(2) of the TRIPS Agreement.

<sup>69</sup> Art 11(2)(c) of the Constitution.

<sup>70</sup> Art 40(3)(b) of the Constitution.

### **2.2.2 Industrial Property Act**

The Industrial Property Act (IPA)<sup>71</sup> implements both the TRIPS Agreement and the Patent Convention Treaty.<sup>72</sup> It repealed the Industrial Property Act of 1989<sup>73</sup>. The IPA is administered by the Kenya Industrial Property Institute (KIPI) established under its section 3. The IPA apart from protecting IPRs also safeguards public health by incorporating TRIPS Agreement flexibilities including parallel importation and compulsory licensing

### **2.2.3 Seeds and Plant varieties Act**

The Seeds and Plant varieties Act<sup>74</sup> provides for, *inter alia*, 'the grant of proprietary rights to persons breeding or discovering new varieties.'<sup>75</sup> It is administered by the Kenya Health Plant Inspectorate Services (KEPHIS).<sup>76</sup>

### **2.2.4 Copyright Act**

The Copyright Act<sup>77</sup> implements not only the TRIPS Agreement but also the Berne Convention. The Act provides a framework for 'copyright in literary, musical and artistic works, audio-visual works, sound recordings, broadcasts and for connected purposes'.<sup>78</sup> It also establishes the Kenya Copyright Board as the administrative unit.<sup>79</sup>

### **2.2.5 Trade Marks Act**

The Trade Marks Act<sup>80</sup> implements the TRIPS Agreement as well as the Trade Mark Law Treaty, the Madrid Agreement and the Banjul Protocol of ARIPO. It provides for the registration and protection of trade marks in Kenya. It is also administered by KIPI.

### **2.2.6 Anti-Counterfeit Act**

The Kenya Anti-Counterfeit Act<sup>81</sup> was enacted in 2008 to combat counterfeit trade by providing for severe penalties than the previous legislations. It is administered by the Anti-Counterfeit Agency.<sup>82</sup>

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<sup>71</sup> Chapter 3 of 2001 Laws of Kenya.

<sup>72</sup> Wekesa (n 31 above), 7.

<sup>73</sup> Chapter 509 Laws of Kenya (repealed by the IPA 2001).

<sup>74</sup> Chapter 326 Laws of Kenya. Commenced on 1 January 1975.

<sup>75</sup> See the preamble of the Act.

<sup>76</sup> See section 33 of the Act providing for a fine not exceeding twenty thousand shillings or to imprisonment for a period not exceeding six months or to both.

<sup>77</sup> Chapter 130 Laws of Kenya. Commenced on 1 February 2003.

<sup>78</sup> See the preamble of the Copyright Act.

<sup>79</sup> Sec 3 of the Copyright Act.

<sup>80</sup> Chapter 506 Laws of Kenya. Commenced on 1 January 1957.

## 2.3 The problem with the Kenya Anti-Counterfeit Act of 2008

Comparatively, the Kenya Anti-Counterfeit Act is the most contested amongst the IPRs legislations in Kenya. The genesis of its problem is predominantly under section 2 which adopts similar exclusive rights as provided for under article 28 of the TRIPS Agreement.<sup>83</sup> However, it prescribes criminal sanctions for their infringement while the TRIPS Agreement prescribes civil remedies.<sup>84</sup> The IPA also proffers civil remedies to enforce patent rights in Kenya by way of injunction, damages and compensation.<sup>85</sup> Below is a step by step explanation of why section 2 is problematic.

One, it defines 'counterfeiting to take certain actions 'without the authority of the owner of intellectual property rights subsisting in Kenya or elsewhere'. This means that IPRs protected anywhere in the world may be enforced in Kenya. It is the first time that Kenya's IPRs legislation extends protection outside its jurisdiction.

Two, 'intellectual property' under the Act has been defined beyond trademarks and copyrights as provided for under the TRIPS Agreement. The most contested inclusion is patent linkage. Thus, under the Anti-Counterfeit Act

"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;

Three, it classifies patent infringement as a counterfeit offence under its sections 32.

It shall be an offence for any person to–

- (a) have in his possession or control in the course of trade, any counterfeit goods;
- (b) manufacture, produce or make in the course of trade, any counterfeit goods;

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<sup>81</sup> Act no 13 of 2008. Commenced on 7 July 2009.

<sup>82</sup> Sec 3 of the Anti-Counterfeit Act.

<sup>83</sup> Article 28 provides that

A patent shall confer on its owner the following exclusive rights:

- (a) Where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making using, offering for sale, selling, or importing for these purposes that product...

<sup>84</sup> Centre for Human Rights *Access to medicines course book (reader)* Advanced human rights course on intellectual property, trade human rights and access to medicines in Africa (undated) 233. File available with the author.

<sup>85</sup> Sec 55 of the IPA.

- (c) sell, hire out, barter or exchange, or offer or expose for sale, hiring out, barter or exchange any counterfeit goods;
- (d) expose or exhibit for the purposes of trade any counterfeit goods;
- (e) distribute counterfeit goods for purposes of trade or any other purpose;
- (f) import into, transit through, tranship within or export from Kenya, except for private and domestic use of the importer or exporter as the case may be, any counterfeit goods;
- (g) in any other manner, dispose of any counterfeit goods in the course of trade.

In order to enforce the IPRs protected under the Anti-Counterfeit Act, Commissioners are given powers to 'seize and detain all suspected counterfeit goods'.<sup>86</sup> In addition, if found guilty, stiff penalties in form hefty fines and long prison sentences can be imposed.<sup>87</sup> Undoubtedly, the Anti-Counterfeit Act has stronger enforcement standards for IPRs beyond the TRIPS Agreement as well as the IPA. As noted above, patent enforcement under the IPA is by way of civil remedies as follows.<sup>88</sup>

The owner of a patent shall have the right -

- (a) to obtain an injunction to restrain the performance or the likely performance, by any person without his authorization, of any of the acts referred to in section 54; and
- (b) to claim damages from any person who, having knowledge of the patent, performed any of the acts referred to in section 54, without the owner's authorization.
- (c) to claim compensation from any person who, without his authorization, performed any of the inventions, claimed in the published application, as if a patent had been granted for that invention.

The Kenyan Anti-Counterfeiting Act, to the extent that it provides for stronger patent protection, 'encourages monopoly situations'.<sup>89</sup> Its heightened pursuit of commercial interests also predisposes it to 'abuse by the patentee himself'.<sup>90</sup> Sangeeta opines that many countries including Kenya already have in place legislations that covers and penalises counterfeiting and piracy, for example, trademark laws, copyrights laws and the penal code.<sup>91</sup> The result is that the promotion of anti-counterfeit legislation would bring about 'chaos of laws and procedures'

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<sup>86</sup> Sec 34 of the Anti-Counterfeit Act.

<sup>87</sup> Sec 35 of the Anti-Counterfeit Act.

<sup>88</sup> Section 55 of the IPA.

<sup>89</sup> As above.

<sup>90</sup> As above.

<sup>91</sup> S Shashikant 'Evaluation of the regional workshop on the enforcement of IPRs for the judiciary and law enforcement officials' (2012) 7 *Third World Network*. Report available on file with the author.

as being witnessed in Kenya.<sup>92</sup> Ultimately, according to Centre for Health, Human Rights and Development (CEHURD),

[t]he likely impact...will be huge implementation costs through monitoring and settling international trade disputes; and IPR border controls and criminalizing possession and trade in IPR infringing goods deters overall trade, in both IPR infringing goods and non-infringing goods.<sup>93</sup>

In 2009, barely after the enactment of the Anti-Counterfeit Act a petition was filed in High Court to try and roll back the strong IPRs protection under the legislation. The *Patricia Asero* case has been discussed extensively in the subsequent sections.

## 2.4 Justiciability of socio-economic rights in Kenya

Before undertaking the analysis of the case, it is imperative to discuss justiciability of socio-economic rights in Kenya. This will put into perspective the arguments proffered by the parties to the *Patricia Asero* case.

Kenya's Independence Constitution did not provide for justiciable socio-economic rights. Kenya, as a dualist state under the Constitution had also failed to transform the various international human rights treaties providing for socio-economic rights into municipal law. This made things difficult for individuals and non-governmental organisations (NGOs) seeking enforcement of these rights in court. However, India's jurisprudence made it possible to protect socio-economic rights by linking them to the enforceable civil and political rights including the right to life and the right to human dignity.<sup>94</sup> It was, therefore, not surprising that at the inception of the first petition in 2009, the right to life and the right to human dignity were relied upon. The enactment of the new Constitution on the 27 August 2010 enshrined socio-economic rights under its Bill of Rights effectively making them justiciable. The right to health was included under Article 43(1)(a). Moreover, the new Constitution made it possible to rely on international treaties while litigating socio-economic rights in Kenya. Kenya currently is a monist state.<sup>95</sup> The new developments made it possible in 2010 to amend the petition to include more fundamental rights under the new Constitution including the right to life under article 28, right

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<sup>92</sup> As above.

<sup>93</sup> 'Rethinking the role of intellectual property policy in the HIV response in East Africa' *Centre for Health, Human Rights and Development (CEHURD)* December 2011 3, <http://www.cehurd.org/wp-content/uploads/downloads/2012/04/EAC-counterfeit-and-ARVs-brief.pdf> (accessed 23 September 2012).

<sup>94</sup> The right to life and human dignity under the Indian Constitution has been interpreted to include various socio-economic rights. For further details see the Indian cases of *Municipal Council Ratlam v Vardhichand and others* (1980) AIR 1622, 1981 SCR (1) 97; and *Bandhua Mukti Morcha vs. Union of India*, (1984) AIR 802, 1984 SCR (2) 67.

<sup>95</sup> See, arts 2(5) & 2(6) of the Constitution.

to human dignity under article 26(1) and right to health under article 43(1) of the Constitution. Below is analysis of the *Patricia Asero* case in full details.

## **2.3 Analysis of the *Patricia Asero* case**

In analysing the *PATRICIA ASERO* case, this study adopts the issue, facts, analysis and the conclusion framework.

### **2.3.1 Issue**

The main issue in this case was whether the Kenya Anti-Counterfeit Act in so far as it restricted access to essential medicines including generics violated the petitioners' constitutional right to life under article 28, right to human dignity under article 26(1) and right to health under article 43(1).

### **2.3.2 Facts**

The facts of this case are stated chronologically.

In 2008, the Kenyan Parliament enacted the Anti-Counterfeit Act providing for amongst other things the establishment of an Anti-Counterfeit Agency and counterfeiting offences.

In 2009, three petitioners describing themselves as living positively with HIV and AIDS filed a petition at the High Court in 2009 complaining that the Kenya Anti-Counterfeit Act infringed on their right to life and the right to human dignity as protected under the previous Constitution.<sup>96</sup>

On 3 November 2010, by way of an amended petition, after the promulgation of the new Constitution,<sup>97</sup> the petitioners extended the infringement to include the right to health protected under article 43(1)(a) of the Constitution.

On 8 March 2010, the petitioners were joined in their petition by AIDS Law Project, a national non-governmental organization operating in Kenya to advance the human rights of persons living with HIV and AIDS, as an interested party.

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<sup>96</sup> The previous Constitution did not provide for justiciable socio-economic rights under its Bill of Rights.

<sup>97</sup> The new Constitution was promulgated on 27 August 2010. It provided for a justiciable socio-economic rights under the Bill of Rights.



On 23 April 2010, the petitioners were granted a temporary order that suspended the application of the Anti-Counterfeit Act to importation of generics pending the hearing and determination of the case.

On 17 January 2011, Mr Anand Grover, the United Nations Special Rapporteur for Health, joined in the petition as an *amicus*.

Submissions were received from both the applicants and the respondents. With regard to the applicants, presentations were made on behalf of the petitioners, the interested party and the *amicus*. The respondent was the Attorney General (AG) representing the government.

On the part of the petitioners,<sup>98</sup> they argued that the Kenya Industrial Property Act<sup>99</sup> had made it easier for the government and non-governmental organisation including Doctors without Borders to import generic ARVs, which improved access to ARVs in Kenya for everyone. In addition, they contended that the Kenya HIV and AIDS Prevention and Control Act<sup>100</sup> recognized their special status as people living with HIV and AIDS by entrenching the right to healthcare services including access to essential medicines at affordable price in its text. Accordingly, the crux of the petitioners' argument can be summarised as follows:<sup>101</sup>

the government has failed to acknowledge and specifically exempt generic drugs and medicines from the definition of counterfeit goods in the Act; it has failed to provide a clear definition of counterfeit goods under section 2 of the Act by defining counterfeit goods 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; it has also failed to take into account the provisions of the HIV and AIDS Prevention and Control Act, 2006 in so far as the petitioners have accrued rights under the said Act and have acquired a legitimate expectation that those rights will be protected; it has failed to clarify the application of the Industrial Property Act, 2001 in so far as the Act allows for the exemption necessary to make generic drugs available in Kenya; it has imposed an undue and unnecessary burden on the consumers of generic drugs and medicines of proving that generic drugs and medicines are not counterfeit goods as defined by the Act.

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<sup>98</sup> See paras 9 – 25 of the decision.

<sup>99</sup> Act No 3 of 2001.

<sup>100</sup> Act No 14 of 2006.

<sup>101</sup> See para 14 of the decision.

On the part of the interested party, AIDS Law Project,<sup>102</sup> the following arguments were made before the High Court. While reiterating the petitioners' case, they argued that the Anti-Counterfeit Act also potentially threatened the right to family life, the right to equality and the right to basic healthcare for children. They also drew the Judge's attention to the fact that the Act allowed for extra-territorial enforcement of IP rights in Kenya which they argued contravened the nature of IPRs protection.

On the part of the *amicus*,<sup>103</sup> he argued that the definition of counterfeiting under the Act would conflate generic medicines. According to the *amicus*, generic medicines are produced without violating any IP rights and are therefore legitimate unlike counterfeit medicines which are illegitimate. Conflating generics as counterfeits would result into limited access of generics in the country thereby putting the petitioners' right to health into jeopardy and possibly resulting into death. These violations, the *amicus* observed, could not be justified on the basis of intellectual property law obligations.

On the part of the respondent,<sup>104</sup> the *proviso* under section 2 of the Anti-Counterfeit Act provided a safeguarded for not only the generic medicines but also other essential goods. The respondent also argued that the definition for counterfeit medicines under the Anti-Counterfeit Act is similar to that of World Health Organisation therefore making it hard to conflate. The respondent concluded by stating that public interest to safeguard the public from the adverse effects, including death, of counterfeit medicines necessitates the implementation of the Anti-Counterfeit Act.

On 20 April 2012, the High Court decision was read out in open court in favour of the petitioners.

### 2.3.3 Analysis

To begin with, in reaching its decision, the High Court established that the socio-economic<sup>105</sup> status of the petitioners made them dependent on 'generic anti-retroviral medication which is much cheaper and therefore more accessible to them.'<sup>106</sup> The petitioners were categorical that

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<sup>102</sup> See paras 26 – 32 of the decision.

<sup>103</sup> See paras 33 – 37 of the decision.

<sup>104</sup> See paras 38 – 43 of the decision.

<sup>105</sup> See paras 44 – 49 of the decision.

<sup>106</sup> See para 50 of the decision.

they were not opposed to the fight against counterfeit products but 'was asking that the legislation should not be contradictory of the state's positive obligation towards them'.<sup>107</sup>

Secondly, the improved access to essential medicines as a result of the utilisation of the parallel importation provisions under the Kenya Industrial Property Act has improved the availability and accessibility of generic ARVs which in turn has greatly enhanced the life and health of persons living with HIV in Kenya including the petitioners.<sup>108</sup> Any measure that would affect access therefore will *ipso facto*, violate the rights of the petitioners to life and health as protected under the Constitution.<sup>109</sup>

Thirdly, Kenya is bound by both its Constitution and international law to protect the right to health. This obligation has both positive and negative duties. The positive aspect requires the government to provide access to healthcare services and medication but the negative duty requires the government not to do anything that would affect access to healthcare services and medication.<sup>110</sup> The anti-counterfeiting legislation therefore insofar as it inhibits access to affordable essential medicines is in violation of the constitution.<sup>111</sup>

Fourthly, in respect to the definition of counterfeiting under section 2, it was argued that the section included generic medicines because they have 'correct ingredients' and 'sufficient active ingredients'.<sup>112</sup> The danger of this is that in a system that focuses on IPRs, such generic drugs can be confiscated under section 32 and 34 of the anti-counterfeiting legislation.<sup>113</sup>

Fifthly, the primary object of the Anti-Counterfeit Act is not to protect consumers, if this were so, it would have placed greater emphasis on standards and quality.<sup>114</sup> However, it was a secondary consideration as illustrated by the *proviso* under section 2.<sup>115</sup> This is misguided because the primary concern of the respondent should be to protect the interests of the petitioners and those infected with HIV and AIDS under its duty on the right to health and access to essential medicines.<sup>116</sup> Accordingly, '[t]here can be no room for ambiguity where the

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<sup>107</sup> Para 22 of the decision.

<sup>108</sup> See para 51 of the decision.

<sup>109</sup> See para 52 of the decision.

<sup>110</sup> See para 66 of the decision.

<sup>111</sup> As above.

<sup>112</sup> See para 78 of the decision.

<sup>113</sup> See para 77 of the decision.

<sup>114</sup> See para 82 of the decision.

<sup>115</sup> See para 83 of the decision.

<sup>116</sup> See para 84 of the decision.

right to health and life of the petitioners and the many other Kenyans who are affected by HIV/AIDS are at stake.<sup>117</sup> The *proviso* under section 2 therefore offers very little help in this regard.<sup>118</sup> Nevertheless, where there is a conflict between the rights of the petitioners and IPRs, as was in this case, the latter must give way to the former.<sup>119</sup>

From the above analysis, the Judge granted the petitioners prayers and ordered as follows with regard to the petition:<sup>120</sup>

- i. The fundamental right to life, human dignity and health as protected and envisaged by Articles 26(1), 28 and 43(1) of the Constitution encompass access to affordable and essential drugs and medicines including generic drugs and medicines
- ii. In so far as the Anti-Counterfeit Act, 2008 severely limits or threatens to limit access to affordable and essential drugs and medicines including generic medicines for HIV and AIDS, it infringes on the petitioner's right to life, human dignity and health guaranteed under Articles 26(1), 28 and 43(1) of the Constitution.
- iii. Enforcement of the Anti-Counterfeit Act, 2008 in so far as it affects access to affordable and essential drugs and medication particularly generic drugs is a breach of the petitioners' right to life, human dignity and health guaranteed under the Constitution.

The Judge recommended a review of section 2 of the Anti-Counterfeit to rid it of patent rights to the end of safeguarding access to generic drugs in Kenya.<sup>121</sup> No orders as to the cost were made.<sup>122</sup>

### **2.3.4 Conclusion**

This case sets important precedent in the arena of access to essential medicines. It provides crucial analysis of the complexities between human rights and IPRs protection. If implemented, the decision would save millions of lives including for persons living with HIV in Kenya like the

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<sup>117</sup> As above.

<sup>118</sup> See para 85 of the decision.

<sup>119</sup> See para 86 of the decision.

<sup>120</sup> See para 87 of the decision.

<sup>121</sup> See para 86 of the decision.

<sup>122</sup> See para 90 of the decision.

petitioners. The importance of this decision, however, also extends to other essential medicines in Kenya including cancer, diabetes and malarial drugs.

## 2.4 Some implications of the decision

As mentioned above, the first and most important implication of this decision is that millions of lives across the board including for persons living with HIV in Kenya will be saved by this one action.<sup>123</sup> The lives to be saved extend also to Uganda, Burundi and Rwanda, amongst others, who depend on Kenyan ports for their shipments.<sup>124</sup>

Two, the decision will also go a long way to 'reduce stock-outs of essential medicines and safeguard access to generic medicines'.<sup>125</sup> Generic medicines have made it possible for public health programmes like the national treatment programme to run smoothly in the country.<sup>126</sup>

Three, the decision will set a positive precedent in the region especially in relation to anti-counterfeit legislations and human rights.<sup>127</sup> In 2010, for example, Uganda revised its anti-counterfeit Bill which was modelled along the Kenyan anti-counterfeit law at the prompting of an earlier conservatory orders issued by the High Court in the *Patricia Asero*. Case.<sup>128</sup> In this way, the case reveals that it does not stand in the way of anti-counterfeiting war but issues of life and death must be taken into account.<sup>129</sup> Therefore, IPRs should not be used to 'legitimately block the import of generic medicines'.<sup>130</sup>

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<sup>123</sup> 'Kenya: High court ruling on anti-counterfeiting law "upholds right to health"' *IRIN humanitarian news and analysis* 25 April 2012, <http://www.irinnews.org/Report/95352/KENYA-High-court-ruling-on-anti-counterfeit-law-upholds-right-to-health> (accessed on 3 September 2012).

<sup>124</sup> As above.

<sup>125</sup> 'Kenya's High Court Strikes down Anti-Counterfeit Act' *Open Society Foundation* 2 May 2012, <http://www.soros.org/press-releases/kenya-s-high-court-strikes-down-anti-counterfeit-act> (accessed 3 September 2012).

<sup>126</sup> 'Health activists welcome High Court judgment on anti-counterfeit law' *Health Action International (HAI) Africa* 20 April 2012, [http://www.haiafrica.org/index.php?option=com\\_content&view=article&id=271:the-high-court-ruling-on-the-kenya-anti-counterfeit-act-2008-&catid=78:news](http://www.haiafrica.org/index.php?option=com_content&view=article&id=271:the-high-court-ruling-on-the-kenya-anti-counterfeit-act-2008-&catid=78:news) (accessed 3 September 2012).

<sup>127</sup> 'Health activists welcome High Court judgment on anti-counterfeit law' *AIDS Law Project* 24 April 2012, <http://www.aidslawproject.org/2012/04/24/press-statement-health-activists-welcome-high-court-judgment-on-anti-counterfeit-law/> (accessed on 3 September 2012).

<sup>128</sup> Musungu (n 51 above), 12.

<sup>129</sup> 'Judgment on generic medicines – Kenya's first victory on the right to health' *Kenya Legal and Ethical Issues Network on HIV & AIDS (KELIN)* 23 April 2012, <http://kelinkenya.org/2012/04/judgment-on-generic-medicines-kenya%E2%80%99s-first-victory-on-the-right-to-health/> (accessed 3 September 2012).

<sup>130</sup> As above.

Four, the case affirms that human rights can legitimately limit enforcement of IPRs.<sup>131</sup> The decision refers to the conflict between IPRs protection and human rights and concludes that the former should give way to the protection of fundamental rights.<sup>132</sup> This is indeed, a precedent setting pronouncement. In practical terms, it means that IPRs protection and enforcement laws should be vetted against human rights compliance.

Lastly, the relevance of anti-counterfeit legislations has also been questioned. According to Musungu,

[t]he truth is that, except for severity of penalties, Kenyan law already provided criminal sanctions for certain types of IP infringement as contemplated by the TRIPS Agreement. Some of the existing laws providing such sanctions included the Industrial Property Act, the Copyright Act, the Penal Code, the Standards Act and the Trade Descriptions Act. There is also an elaborate legal framework, backed by criminal sanctions, to ensure the safety of medicines in Kenya. Such laws include the Medical Practitioners and Dentists Act, Narcotic Drugs and Psychotropic Substances Act, Pharmacy and Poisons Act, the Public Health Act and the Use of Poisonous Substances Act. Institutions to implement these laws also exist.<sup>133</sup>

The government and the legislature must 'think hard and clearly as to what (the) objectives are, who is being served and why.'<sup>134</sup> The UNAIDS, however, seems to support strong anti-counterfeiting laws so long as they do not jeopardize access to generic medicines.<sup>135</sup> Adeyemi argues that because counterfeiting is a species of organised crime functioning as a criminal act, it must be combated under a framework that includes criminal justice system.<sup>136</sup> Criminal law therefore cannot be substituted but its scope can and should be limited to include only those crimes that exhibit the nature of organised crimes. Generic production and marketing cannot be said to meet this criteria.

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<sup>131</sup> 'Landmark decision on medicines and anti-counterfeiting law by Kenyan High Court' *Don't trade our lives away blog* 24 April 2012, <http://donttradeourlivesaway.wordpress.com/2012/04/24/landmark-decision-on-medicines-and-anti-counterfeiting-law-by-kenyan-high-court/> (accessed 2 October 2012).

<sup>132</sup> See para 86 of the decision.

<sup>133</sup> 'Sections of the Kenya Anti-Counterfeit Act struck down as a threat to fundamental human rights' *IQ Sensato* 23 April 2012, <http://www.iqsensato.org/blog/2012/04/23/kenya-anti-counterfeiting-act-struck-down/> (accessed 3 September 2012).

<sup>134</sup> As above.

<sup>135</sup> 'UNAIDS (n 28 above)

<sup>136</sup> Consultation with AA Adeyemi, Professor Emeritus at University of Lagos, Faculty of Law, 24 October 2012 at University of Lagos, faculty of Law.

## 2.5 Conclusion

From the above analysis of the *Patricia Asero* case, it emerges that the Kenya Anti-Counterfeit Act contradicts other IPRs legislations. Therefore, it is important that the government of Kenya considers revising and amending the Kenya Anti-Counterfeit Act to, amongst other things, safeguard access to essential medicines including generics. This is because millions of lives, in Kenya and beyond are at stake if the Act is applied in its current form to essential medicines.

## Chapter three

### 3. Legal and socio-economic imperatives for safeguarding access to essential medicines in Kenya

#### 3.1 Introduction

This Chapter makes a case for safeguarding access to essential medicines in Kenya by analysing the legal and socio-economic imperatives. It explores the human rights instruments in both 'hard' and 'soft' law that entrench the right to health and support scaling up of access to essential medicines in Kenya. It also discusses the socio-economic condition of the country and why TRIPS plus measures as provided for under the Kenya Anti-Counterfeit Act are undesirable particularly the patent linkage.

#### 3.2 The nature of state obligations and the normative contents under the right to health

The nature of states' obligation and the normative content of the fundamental right to health is crucial to link Kenya with its obligation with regard to guaranteeing access to essential medicines including generics. The Committee on Economic, Social and Cultural Rights (CESCRs) jurisprudence codified in form of General Comments offers legitimate interpretation of these two issues.

To begin with, the CESCR General Comment No 3 outlines the nature of member states' obligation under the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>137</sup> It calls for members to put in place appropriate measures including legislation and also to make judicial remedies available in respect of socio-economic rights.<sup>138</sup> Kenya satisfies both obligations since it has in place justiciable socio-economic rights in its Bill of Rights under the Constitution. States are required to move 'expeditiously and effectively as possible' towards the full realization of the right to health alongside other socio-economic rights.<sup>139</sup> By implication, Kenya has no luxury of time to implement the *Patricia Asero case* decision. Implementation of the decision must be undertaken expeditiously. Lastly, Kenya is at no liberty to derogate from

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<sup>137</sup> International Covenant on Economic, Social and Cultural Rights, 16 December 1966, 993 U.N.T.S. 3; S. Exec. Doc. D, 95-2 (1978); S. Treaty Doc. 95-20, 6I.L.M. 368 (1967), <http://www2.ohchr.org/english/law/cescr.htm> (accessed 22 August 2012). Kenya acceded to the Convention on 1 May 1972. It reserved Art 10(2)3.

<sup>138</sup> General Comment No 3 14 December 1990 (UN Doc. E/1991/23), <http://www.unhcr.org/refworld/docid/4538838e10.html> (accessed 11 September 2012) para 5. In this regard, Kenya is compliant since it provides for justiciable ESCRs under its Bill of Rights including the right to health under Article 43(1).

<sup>139</sup> As above, para 9.



its obligations under the right to health unless it can fully justify it taking into account the 'totality of the rights' in the context of the 'full use of the maximum available resources'.<sup>140</sup> CESCR General Comment No 3 sets very strict rules with regard to the nature of states obligations under the ICESCR. These can be summarised as follows: (a) states are to provide for justiciable socio-economic rights nationally; (b) states are to implement socio-economic rights in an expeditious and effective manner; and (c) derogation from obligations under the ICESCR are generally not permitted and the very limited exceptions allowed do not extend to core obligations under the right to health.

The CESCR General Comment No 14<sup>141</sup> looks specifically into the right to health. It posits that the right to health must take into account both 'the individual's biological and socio-economic preconditions and a state's available resources'.<sup>142</sup> It provides for core contents which may not be derogated from by a member state and includes 'essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs'.<sup>143</sup> Retrogressive measures incompatible with a core obligation constitute, *ipso facto*, an infringement under the right.<sup>144</sup> Infringements may be through commission or omission. Commission means 'formal repeal or suspension of legislation necessary' to facilitate the realisation of the right to health or the 'adoption of legislations or policies' that are in direct conflict with the state's obligation under the right to health. This is also commonly referred to as 'positive obligation'. The adoption of the Kenya Anti-counterfeit Act is a good example of a violation of a positive obligation by Kenya under the right to health. Omission, also commonly referred to as 'negative obligation', include failure to take necessary steps towards the full realization of the right to health by for example, failing to put in place relevant policies or implementing relevant laws.<sup>145</sup>

Does IPRs have a place in human rights discourse and how do they affect the right to health? The CESCR General Comment No 17<sup>146</sup> provides that higher standards of IPRs protection should not limit other rights in the ICESCR including the right to food, health and

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<sup>140</sup> As above.

<sup>141</sup> General Comment No 14 8 November 2011 (UN Doc. E/C.12/2000/4), <http://www.unhcr.ch/tbs/doc.nsf/%28symbol%29/E.C.12.2000.4.En> (accessed 11 September 2012).

<sup>142</sup> As above, para 9.

<sup>143</sup> As above, para 43(d).

<sup>144</sup> As above, para 48.

<sup>145</sup> As above, para 48-49.

<sup>146</sup> General Comment No 17 on the right of everyone to benefit from the protection of the moral and material interest resulting from any scientific, literary or artistic production of which he or she is the author 12 January 2006 (UN Doc. E/C.12/GC/17), <http://www.unhcr.org/refworld/pdfid/441543594.pdf> (accessed on 3 September 2012).

education.<sup>147</sup> The duty of the state under Article 24 which addresses the issue of IPRs requires the state, amongst other things to prevent 'unreasonable high cost for access to medicines, plant seeds or other means of food production, or for schoolbooks and learning materials'.<sup>148</sup> In practical terms, this may include making generic competition for medicines more accessible because they are affordable and they assist in driving medicine prices low because of competition. Secondly, providing for stronger patent protection as does the Kenya Anti-Counterfeit Act encourages monopoly which in turn translates to high medicine prices. These two scenarios are not tenable for a country that is a member of the ICESCR like Kenya.

At the regional front, the Principles and Guidelines on the Implementation of the Economic, Social and Cultural Rights in the African Charter on Human and Peoples' Rights (AU-ESCR Principles and Guidelines)<sup>149</sup> interprets the right to health to encompass both health care and its underlying determinants.<sup>150</sup> More importantly, the state, under this right, is obliged to provide 'essential drugs to all those who need them as periodically defined under the WHO Action Programme on Essential Drugs, and particularly anti-retroviral drugs'.<sup>151</sup>

### **3.3 Legal imperatives**

This part is divided into two parts. Part one discusses the 'hard' law and part two the 'soft' law that provide the basis of holding Kenya accountable to its right to health obligations including guaranteeing access to essential medicines.

#### **3.3.1 'Hard' law**

Kenya's legal commitments with regard to the right to health transcend the national laws and extend to the sub-regional, regional and international laws. Pursuant to article 2(6) of Kenya's Constitution,<sup>152</sup> international treaties ratified by Kenya also form part of the Kenyan laws effectively making Kenya a monist State.

The first point of reference with regard to the protection of the right to health is article 43(1)(a) of the Constitution of Kenya. It provides that '[e]very person has the right to the highest attainable standard of health, which includes the right to health care services, including

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<sup>147</sup> As above, para 11.

<sup>148</sup> As above, para 35.

<sup>149</sup> African Union Economic Social and Cultural Rights Principles and Guidelines (2009), [www.interrupt.org/economic-social-and-cultural-rights-principles-and-guidelines/index.html](http://www.interrupt.org/economic-social-and-cultural-rights-principles-and-guidelines/index.html) (accessed 11 September 2012).

<sup>150</sup> As above, para. 61.

<sup>151</sup> As above, paragraph 67

<sup>152</sup> The Constitution of Kenya (27 August 2010) (Kenya).

reproductive health care' effectively making the right to health a justiciable right in Kenya.<sup>153</sup> Other relevant constitutional provisions include article 53(1)(c) and article 56(e) on the rights of the child and the rights of minorities and marginalized groups respectively. Article 46 on the protection of consumers' health is also applicable in this regard. By legislations, the HIV and AIDS Prevention and Control Act (HAPCA)<sup>154</sup> and the Children Act<sup>155</sup> entrench the right to health. Section 19 of the HAPCA provides that '[t]he Government shall, to the maximum of its available resources, take the steps necessary to ensure access to health care services, including access to essential medicines at affordable prices by persons with HIV or AIDS and those exposed to the risk of HIV infection.' In the same manner, section 9 of the Children Act bestows the responsibility to provide the right to health and medical care for children on parents and the Government. Kenya is in the process of enacting the Health Law which will implement article 43(1)(a) of the Constitution. Once enacted, it will further entrench the right to health in Kenya.<sup>156</sup>

On the sub-regional front, there are a number of regional economic treaties that have direct implications on the right to health in Kenya. First, the East African Community (EAC) Treaty<sup>157</sup> provides for cooperation amongst members in the area of health to address pandemics and epidemics of 'communicable and vector-borne diseases such as HIV and AIDS, cholera, malaria, hepatitis and yellow fever'.<sup>158</sup> The EAC Treaty also encourages cooperation in the area of drug policy<sup>159</sup> and drug registration<sup>160</sup>. The EAC has in place a HIV and AIDS Unit (HAU) complete with a Strategic Plan, 2007-2012.<sup>161</sup> The overall strategic objective of the HAU is to 'strengthen and expand responses to HIV and AIDS in East Africa by scaling up access'. On 23 April 2012, the East African Legislative Assembly passed the crucial EAC HIV and AIDS

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<sup>153</sup> Article 43(1)(a) of the Kenyan Constitution.

<sup>154</sup> HIV and AIDS Prevention and Control Act (Act No 14 of 2006 Laws of Kenya).

<sup>155</sup> Children Act (Act No 8 of 2001) (Kenya).

<sup>156</sup> Section 2(c)(1) of the Health Law draft entitles '[a] persons living in Kenya to the progressive realization of their right to the highest attainable standard of health, including reproductive health care and the right to emergency medical treatment.'

<sup>157</sup> East African Community (EAC) Treaty (Signed in 30 November 1999 and entered into force 7 July 2000), [http://www.comesa.int/index.php?option=com\\_content&view=article&id=28:comesa-treaty&catid=17:council-decisions&Itemid=60](http://www.comesa.int/index.php?option=com_content&view=article&id=28:comesa-treaty&catid=17:council-decisions&Itemid=60) (accessed 23 October 2012).

<sup>158</sup> Article 118(a) of the EAC Treaty.

<sup>159</sup> Article 118(c) of the EAC Treaty.

<sup>160</sup> Article 118(d) of the EAC Treaty.

<sup>161</sup> For a copy of the strategic plan visit [http://www.eac.int/health/index.php?option=com\\_content&view=article&id=57&Itemid=110](http://www.eac.int/health/index.php?option=com_content&view=article&id=57&Itemid=110) (accessed 23 October 2012).

Prevention and Management Bill, 2012.<sup>162</sup> Article 33 of the Bill recognises the right of access to healthcare services for persons living with HIV. The measures to be put in place include use of TRIPS Agreement flexibilities.<sup>163</sup> The second point of reference is the Intergovernmental Authority on Development (IGAD) Treaty.<sup>164</sup> Amongst other things, it seeks to promote joint development strategies and gradual harmonization of macro-economic policies and programmes in the social, technological and scientific fields;<sup>165</sup> as well as the harmonization of policies with regard to trade, customs, transport, communications, agriculture, and natural resources, and the promotion of free movement of goods, services, and people within the region have a direct implication on access to essential medicines.<sup>166</sup> On 20 December 2010, Ministers of Health and or Ministers in charge of HIV and AIDS made a Declaration in Ethiopia to maintain the political will to scale up access to HIV prevention, treatment, care and support.<sup>167</sup> Lastly, the Common Market for Eastern and Southern Africa (COMESA) Treaty<sup>168</sup> also provides for cooperation in the area of health, particularly, by providing appropriate mechanisms for joint actions against epidemics such as AIDS, cholera, malaria, hepatitis and yellow fever.<sup>169</sup> Cooperation is also encouraged in the area of national drug policies.<sup>170</sup> In order to implement HIV and AIDS programmes, there is established a framework for the multi-sectoral programme on HIV & AIDS for COMESA, 2012-2015.<sup>171</sup> In this framework, access to life-saving medicines has been identified as an overriding priority at the highest political level due to heavy dependence on

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<sup>162</sup> For a copy of the Bill, visit

[http://www.eannaso.org/index.php?option=com\\_docman&task=cat\\_view&Itemid=10&gid=74&orderby=dmdate\\_published&ascdesc=DESC&lang=en](http://www.eannaso.org/index.php?option=com_docman&task=cat_view&Itemid=10&gid=74&orderby=dmdate_published&ascdesc=DESC&lang=en) (accessed 23 October 2012). The Bill is awaiting assent by EAC Heads of States.

<sup>163</sup> See article 33(3)(a) of the Bill.

<sup>164</sup> The Intergovernmental Authority on Development (IGAD) in Eastern Africa was created in 1996 to supersede the Intergovernmental Authority on Drought and Development (IGADD) which was founded in 1986, [www.igad.int/etc/agreement\\_establishing\\_igad.pdf](http://www.igad.int/etc/agreement_establishing_igad.pdf) (accessed 23 October 2012).

<sup>165</sup> Article 7(a) of the IGAD Treaty. By necessary implication, HIV and AIDS and access to medicines fall in this category.

<sup>166</sup> Article 7(b) of the IGAD Treaty. Particularly, in-transit anti-counterfeiting measures are relevant in this regard.

<sup>167</sup> Declaration of the fifth IGAD Ministerial Committee meeting on health and HIV and AIDS signed in Addis Ababa, Ethiopia on this 20 December 2010, [http://igad.int/index.php?searchword=HIV&ordering=&searchphrase=all&option=com\\_search#content](http://igad.int/index.php?searchword=HIV&ordering=&searchphrase=all&option=com_search#content) (accessed 23 October 2012).

<sup>168</sup> Signed on 5th November 1993 in Kampala, Uganda and was ratified a year later in Lilongwe, Malawi on 8th December 1994.

<sup>169</sup> Article 110(2)(b) of the COMESA Treaty. According to the COMESA website the overall goal of the multisectoral programme on HIV and AIDS is to contribute to the reduction of the epidemic and also mitigate its negative impacts in the COMESA region.

<sup>170</sup> Article 110(2)(d) of the COMESA Treaty.

<sup>171</sup> For a copy of the programme, visit [programmes.comesa.int/attachments/article/82/120714\\_COMESA\\_HIV\\_AIDS\\_Multisectoral\\_programme.pdf](http://programmes.comesa.int/attachments/article/82/120714_COMESA_HIV_AIDS_Multisectoral_programme.pdf) (accessed 23 October 2012).

importation low-priced medicines.<sup>172</sup> It has also been acknowledged under COMESA that enforcement of anti-counterfeiting measures 'can also constitute a barrier to legitimate trade.'<sup>173</sup>

At the Regional level, Kenya has acceded/ratified a number of human rights instruments codifying the right to health. These include article 16 of the African Charter on Human and Peoples' Rights (African Charter);<sup>174</sup> article 14(1) of the Protocol to the African Charter on the Rights of the Women (African Women's Protocol);<sup>175</sup> article 14(1) of the Protocol to the African Charter on the Rights of the Child (African Children's Protocol);<sup>176</sup> and article 16 of the African Youth Charter<sup>177</sup>. The African Women's Protocol and the African Youth Charter have been signed but not yet ratified by Kenya.

At the international level, the Universal Declaration of Human Rights (UDHR)<sup>178</sup> provides for the right to health under its article 25. Even though UDHR is not technically legally binding, ICESCR addresses this concern by including article 12(1) on the right to health in a language that is legally enforceable. Other main instruments providing for the right to health at the international level include the Convention on the Elimination of All Forms of Discrimination

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<sup>172</sup> As above, para 99.

<sup>173</sup> Sector strategy for access to medicines in COMESA (2011) 6, <http://www.trademarksa.org/news/comesa-sector-strategy-access-medicine> (accessed 27 October 2012).

<sup>174</sup> African Charter on Human and Peoples' Rights (African Charter ), adopted on 27 June 1981, CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force 21 October 1986, [http://www.africa-union.org/official\\_documents/treaties\\_%20conventions\\_%20protocols/banjul%20charter.pdf](http://www.africa-union.org/official_documents/treaties_%20conventions_%20protocols/banjul%20charter.pdf) (accessed 21 August 2012). Kenya acceded to the African Charter on 23 January 1992.

<sup>175</sup> Protocol to the African Charter on Human and People's Rights on the Rights of Women in Africa, adopted by the 2<sup>nd</sup> Ordinary Session of the Assembly of the Union, Maputo, CAB/LEG/66.6 (13 September 2000); reprinted in 1 Afr. Hum. Rts. L.J. 40, entered into force 25 November 2005, <http://www.unhcr.org/refworld/docid/3f4b139d4.html> (accessed 21 August 2012). Kenya is yet to adopt/accede to the African Women's Protocol. However, it signed the Protocol on the 17 December 2003 signaling its commitment to accede to the Protocol.

<sup>176</sup> Protocol to the African Charter on the Rights and Welfare of the Child, adopted in Addis Ababa, Ethiopia July 1990, OAU Doc. CAB/LEG/24.9?49 (1990), entered into force 29 November 1999, [www.africa-union.org/root/au/Documents/Treaties/Text/A.%20C.%20ON%20THE%20RIGHT%20AND%20WELF%20OF%20CHI LD.pdf](http://www.africa-union.org/root/au/Documents/Treaties/Text/A.%20C.%20ON%20THE%20RIGHT%20AND%20WELF%20OF%20CHI LD.pdf) (accessed 21 August 2012). Kenya acceded to the Protocol on 25 July 2000.

<sup>177</sup> African Youth Charter, adopted by the Seventh Ordinary Session of the Assembly, held in Banjul, The Gambia on 2 July 2006, [www.africa-union.org/root/au/Documents/Treaties/Text/African\\_Youth\\_Charter.pdf](http://www.africa-union.org/root/au/Documents/Treaties/Text/African_Youth_Charter.pdf) (accessed 21 August 2012). Kenya signed the Charter on 28 June 2008 signaling its commitment to accede to the Charter.

<sup>178</sup> Universal Declaration of Human Rights, Adopted by the General Assembly on 10 December 1948, 217 A (III), <http://www.ohchr.org/en/udhr/pages/introduction.aspx> (accessed 22 August 2012).

against Women (CEDAW),<sup>179</sup> the Convention on the Rights of the Child (CRC)<sup>180</sup> and the Convention on the Rights of Persons with Disabilities (CRPD)<sup>181</sup>.

### 3.3.2 'Soft' law

There are a number of instruments which do not necessarily create legal obligations but are crucial since they have implications for the right to health and access to essential medicines in the country.

To start with, the UN Millennium Development Goals (MDGs)<sup>182</sup> Goal 4 on reduction of child mortality, Goal 5 on improving maternal care, and Goal 6 on combating HIV and AIDS, malaria and other diseases are relevant in our study. In 2009, a report on the progress of the MDGs in Africa indicated that the HIV prevalence rate has been on a downward trend. The prevalence rate in sub-Saharan Africa declined to five percent and AIDS-related deaths also decreased from 2 million in 2001 to 1.4 million in 2007.<sup>183</sup> As a result of the reduction of AIDS-related deaths globally, currently, 'an estimated 34 million were living with HIV, up 17 percent from 2001'.<sup>184</sup> The second document in this regard is the Ottawa Charter for Health Promotion<sup>185</sup> which is a WHO document aimed at promoting health. The Charter provides that

[h]ealth promotion is the process of enabling people to increase control over, and to improve, their health. To reach a state of complete physical, mental and social well-being, an individual or group must be able to identify and to realise the aspirations, to satisfy needs, and to change or cope with the environment. Health is, therefore, seen as a resource for everyday life, not the objective of living. Health is a positive concept emphasizing social and personal resources, as well

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<sup>179</sup> Convention on the Elimination of All Forms of Discrimination against Women, Dec. 18, 1979, 1249 U.N.T.S. 13; 19 I.L.M. 33(1980), [www.un.org/womenwatch/daw/cedaw/cedaw23/lithuania.pdf](http://www.un.org/womenwatch/daw/cedaw/cedaw23/lithuania.pdf) (accessed 22 August 2012). Kenya ratified the Convention on 9 March 1984.

<sup>180</sup> Convention on the Rights of the Child, Nov. 20, 1989, 1577 U.N.T.S. 3; 28 I.L.M. 1456(1989), [www2.ohchr.org/english/law/pdf/crc.pdf](http://www2.ohchr.org/english/law/pdf/crc.pdf) (accessed 22 August 2012). Kenya ratified the Convention on 30 July 1990.

<sup>181</sup> Convention on the Rights of Persons with Disabilities, G.A. Res. 61/106, Annex I, U.N. GAOR, 61st Sess., Supp. No. 49, at 65, U.N. Doc. A/61/49 (2006), *entered into force* May 3, 2008, [www.un.org/disabilities/default.asp?id=150](http://www.un.org/disabilities/default.asp?id=150) (accessed 22 August 2012). Kenya acceded to the Convention on 19 May 2008.

<sup>182</sup> The Millennium Development Goals (2000), [www.un.org/millenniumgoals/](http://www.un.org/millenniumgoals/) (accessed on 18 September 2012).

<sup>183</sup> Assessing progress in Africa towards the Millennium Development Goals (2009) 29, <http://www.un.org/millenniumgoals/reports.shtml> (accessed 18 September 2012).

<sup>184</sup> Millennium Development Goals Report (2012) 39, <http://www.un.org/millenniumgoals/reports.shtml> (accessed 18 September 2012).

<sup>185</sup> Ottawa Charter for Health Promotion (1986), [www.who.int/healthpromotion/conferences/previous/ottawa/en/](http://www.who.int/healthpromotion/conferences/previous/ottawa/en/) (accessed 18 September 2012).

as physical capacities. Therefore, health promotion is not just the responsibility of the health sector, but goes beyond healthy life-styles to well-being.<sup>186</sup>

The emphasis with regard to health should therefore be on the 'well-being' of individuals all over the world including persons living with HIV and AIDS. Thirdly, the Declaration of Commitment on HIV/AIDS of 2001<sup>187</sup> marked a new era of commitment with regard to the fight against HIV and AIDS in the world. The 2001 Declaration amongst other things achieved the coordination and intensification of interventions to combat HIV and AIDS globally.<sup>188</sup> HIV and AIDS was also identified as a potential obstacle in achieving MDGs adopted earlier.<sup>189</sup> Access to medications in the context of pandemics such as HIV/AIDS was reaffirmed under the right to health.<sup>190</sup> In 2006, the Political Declaration on HIV and AIDS<sup>191</sup> reiterated the 2001 Political Declaration on HIV and AIDS. However, the 2006 Political Declaration on HIV and AIDS emphasized on intensifying of prevention of HIV infection responses internationally, regionally and nationally.<sup>192</sup> Participants committed themselves to overcome 'legal, regulatory or other barriers that block access to...medicines...'<sup>193</sup> They also resolved to assist developing countries to utilize TRIPS Agreement flexibilities.<sup>194</sup> In 2011, the Political Declaration on HIV and AIDS<sup>195</sup> identified sub-Saharan Africa as worst hit by the HIV and AIDS scourge and reiterated the need to scale up HIV and AIDS response in the region.<sup>196</sup> Access to safe, effective and affordable medicine was also reiterated as crucial to achieving the rights to health.<sup>197</sup> The critical importance of affordable medicines including generics was also acknowledged in scaling up

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<sup>186</sup> As above, part 1 on health promotion.

<sup>187</sup> Political Declaration on HIV and AIDS, adopted by the United Nations General Assembly Special Session on 25-27 June 2001, [www.unaids.org/en/aboutunaids/unitednationsdeclarationsandgoals/2001declarationofcommitmentonhivaids/](http://www.unaids.org/en/aboutunaids/unitednationsdeclarationsandgoals/2001declarationofcommitmentonhivaids/) (accessed 18 September 2012).

<sup>188</sup> As above, para 1.

<sup>189</sup> As above, para 5.

<sup>190</sup> As above, para 15.

<sup>191</sup> Political Declaration on HIV and AIDS 2006, UN Doc. No.: A/RES/60/262, [data.unaids.org/pub/report/2006/20060615\\_hlm\\_politicaldeclaration\\_ares60262\\_en.pdf](http://data.unaids.org/pub/report/2006/20060615_hlm_politicaldeclaration_ares60262_en.pdf) (accessed 18 September 2012).

<sup>192</sup> As above, para 22.

<sup>193</sup> As above, para 24.

<sup>194</sup> As above, para 44.

<sup>195</sup> Political Declaration on HIV and AIDS 2011, UN Doc. No.: A/RES/65/277, [www.unaids.org/en/aboutunaids/unitednationsdeclarationsandgoals/2011highlevelmeetingonaids/](http://www.unaids.org/en/aboutunaids/unitednationsdeclarationsandgoals/2011highlevelmeetingonaids/) (accessed on 18 September 2012).

<sup>196</sup> As above, para 9.

<sup>197</sup> As above, para 32.

access to affordable HIV treatment.<sup>198</sup> Members were advised to adopt enforcement measures for IPRs that are compliant with the TRIPS Agreement in order to protect public health.<sup>199</sup>

At the regional level, there are a number of instruments with implications for HIV and AIDS and the right to health. The 2001 Abuja Declaration and Plan of Action on HIV and AIDS, Tuberculosis, Malaria and Other Related Infectious Diseases<sup>200</sup> declared a State of Emergency in the continent as a result of the HIV and AIDS pandemic.<sup>201</sup> In this regard, the fight against HIV and AIDS was a priority issue at the national level of the respective States.<sup>202</sup> It was also resolved in this meeting to 'enact and utilize appropriate legislation and international trade regulations to ensure the availability of drugs at affordable prices'.<sup>203</sup> In 2003, the Maputo Declaration on HIV and AIDS, Tuberculosis, Malaria and Other Related Infectious Diseases<sup>204</sup> reaffirmed the commitment of the 2001 Abuja Declaration. In its preamble, it noted that those who are mostly affected by the HIV and AIDS scourge were poor women, children and young people. In the Maputo Declaration, States expressed their determination to 'ensure that all opportunities for scaling up treatment for HIV and AIDS [were] pursued energetically and creatively'.<sup>205</sup> In 2005, the Gaborone Declaration on a Roadmap towards Universal Access to Prevention, Treatment and Care<sup>206</sup> was adopted to scale up treatment to more than a third of the people in the continent who had no access to essential medicines.<sup>207</sup> TRIPS-plus provisions being adopted in the context of regional economic communities were also condemned for the first time.<sup>208</sup> Utilisation of TRIPS Agreement flexibilities and promotion of local production of generic medicines in the region was encouraged.<sup>209</sup> Trade Ministers were also instructed to find solutions at the WTO by, amongst other things, revising the TRIPS Agreement to remove

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<sup>198</sup> Para. 35 of the 2011 Political Declaration.

<sup>199</sup> As above.

<sup>200</sup> Abuja Declaration and Plan of Action on HIV and AIDS, Tuberculosis, Malaria and Other Related Infectious Diseases (2001), Doc. No.: OAU/SPS/ABUJA/3, [www.un.org/ga/aids/pdf/abuja\\_declaration.pdf](http://www.un.org/ga/aids/pdf/abuja_declaration.pdf) (accessed 18 September 2012).

<sup>201</sup> As above, para. 22.

<sup>202</sup> As above, para. 23.

<sup>203</sup> As above, para. 31.

<sup>204</sup> Maputo Declaration on HIV and AIDS, Tuberculosis, Malaria and Other Related Infectious Diseases (2003), Doc. No.: Assembly/AU/Decl.6(II), [www.iag-agi.org/bdf/en/corpus\\_document/fiche-document-1195.html](http://www.iag-agi.org/bdf/en/corpus_document/fiche-document-1195.html) (accessed 18 September 2012).

<sup>205</sup> As above, para. 4.

<sup>206</sup> Gaborone Declaration on a Roadmap towards Universal Access to Prevention, Treatment and Care (2005), Doc. No.: CAMH/Decl.1(II), [www.africa-union.org/root/au/Conferences/Past/2006/March/SA/Mar6/GABORONE\\_DECLARATION.pdf](http://www.africa-union.org/root/au/Conferences/Past/2006/March/SA/Mar6/GABORONE_DECLARATION.pdf) (accessed 18 September 2012).

<sup>207</sup> As above, preamble.

<sup>208</sup> As above, para. 5.

<sup>209</sup> As above, para. 3.



procedural difficulties in exporting and importing generic medicines.<sup>210</sup> In 2006, the Brazzaville Commitment on Scaling Up Towards Universal Access to HIV and AIDS Prevention, Treatment, Care and Support in Africa by 2010<sup>211</sup> was adopted and it reiterated regional economic entities utilisation of TRIPS Agreement flexibilities and other measures including setting up of regional and national bulk purchasing, technology transfer, south-south collaboration and sub-regional production of AIDS-related medicines.<sup>212</sup> In the same year, the Abuja Call for Accelerated Action Towards Universal Access to HIV and AIDS, Tuberculosis and Malaria Services in Africa<sup>213</sup> was also adopted and it identified as one of the challenges of fighting HIV and AIDS, inadequate access to essential medicines.<sup>214</sup> However, its progress report covering the period 2006-2010<sup>215</sup> revealed that HIV and AIDS treatment had increased in the Eastern and Southern Africa region reaching about 2.4million persons representing an increase of 43 percent from the previous year.<sup>216</sup> However, there were still more than half of those in need who were not on anti-retrovirals (ARVs) treatment as there was the challenge of retention or sticking to treatment.<sup>217</sup> The report however was optimistic that local manufacturing of ARVs in the coming years would further reduce prices. Currently, Africa has only six plants producing generic medicines for local consumption.<sup>218</sup> It decried the fact that most countries were yet to adopt or worst still apply policies and legislations protecting, amongst other things, the right to health posing a major challenge.<sup>219</sup> Another document that was adopted in that year is the Africa's Common Position to the UN General Assembly Special Session on AIDS (2006)<sup>220</sup> where African countries presented a joint position to the UN. In this report, it was acknowledged that 70% of adults and 80% of children as well as two-thirds of the nearly 22 million AIDS-related deaths worldwide come from Africa.<sup>221</sup> However, African countries were still concerned that access to 'effective

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<sup>210</sup> As above, para. 4.

<sup>211</sup> Brazzaville Commitment on Scaling Up Towards Universal Access to HIV and AIDS Prevention, Treatment, Care and Support in Africa by 2010 (2006), [www.unaidsrstes.org/prvs/sites/default/files/brazzaville\\_declaration\\_.pdf](http://www.unaidsrstes.org/prvs/sites/default/files/brazzaville_declaration_.pdf) (accessed 18 September 2012).

<sup>212</sup> As above, para. 6(m).

<sup>213</sup> Abuja Call for Accelerated Action Towards Universal Access to HIV and AIDS, Tuberculosis and Malaria Services in Africa (2006), <http://www.africa-union.org/root/au/conferences/past/2006/may/summit/summit.htm> (accessed 18 September 2012).

<sup>214</sup> As above, para. 7.

<sup>215</sup> Abuja Declaration progress report (2006), AU Doc. No.: MIN/Sp?AU/CAMH4/3, [www.africa-union.org/root/UA/Conferences/2010/juillet/Summit\\_2010\\_b/doc/SA/ABUJA-PROGRESS%20REPORT%20MAY%202010.doc](http://www.africa-union.org/root/UA/Conferences/2010/juillet/Summit_2010_b/doc/SA/ABUJA-PROGRESS%20REPORT%20MAY%202010.doc) (accessed on 18 September 2012).

<sup>216</sup> As above, 27.

<sup>217</sup> As above, 28.

<sup>218</sup> As above, 33.

<sup>219</sup> As above, 44.

<sup>220</sup> Africa's Common Position to the UN General Assembly Special Session on AIDS (2006), Doc. No.: Sp/Assembly/ATM/3(1) Rev 2, [www.africa-union.org/root/au/conferences/past/2006/may/summit/doc/UNGASS.pdf](http://www.africa-union.org/root/au/conferences/past/2006/may/summit/doc/UNGASS.pdf) (accessed 18 September 2012).

<sup>221</sup> As above, para 3.

and affordable preventive, care and treatment measures' including essential medicines was a huge challenge in Africa.<sup>222</sup> Accordingly, African countries pledged, *inter alia*, to 'scale-up and accelerate a public health approach for universal access to prevention, treatment, care and support for HIV and AIDS, tuberculosis and malaria'.<sup>223</sup>

### 3.4 Socio-economic imperatives

According to Salomon, the stark inequality in Africa compared to the rest of the world is 'needlessly unfair'.<sup>224</sup> About 45% or more of Africans live below the poverty line.<sup>225</sup> In numerical terms, this translates into about 330million poor Africans.<sup>226</sup> In Kenya, more than half of the population lives in extreme poverty.<sup>227</sup> In percentage terms, this translates into 56% of the population.<sup>228</sup> The majority of the Kenyan population like many other developing countries is poor.

About 80% of anti-retroviral drugs used by 6.6 million people in middle and low income countries are generic medicines.<sup>229</sup> Accordingly, due to high poverty levels in Kenya, most public health programmes are dependent on generic medicines which are comparatively cheaper than branded medicines. Maybarduk observes that

[o]ver the last ten years, global competition and generic medicines have produced a revolution in HIV/AIDS treatment, reducing prices from \$10,000 to \$ 100 per person per year in developing countries and enabling more than five million people worldwide to have access to lifesaving antiretroviral therapy<sup>230</sup>

Wider access to generic medicines in Kenya has certain practical advantages. It has enabled the country to reduce AIDS-related deaths by 29% higher than the global 20% drop in AIDS-related deaths.<sup>231</sup> At the end of 2011, it was projected that out of 1.6million people living

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<sup>222</sup> As above, para 42-43.

<sup>223</sup> As above, para 46.

<sup>224</sup> M Salomon 'Why should it matter that others have more? Poverty, inequality and the potential of international human rights law' (2011) 37(5) *Review of International Studies* 2138.

<sup>225</sup> As above, xxiv.

<sup>226</sup> As above.

<sup>227</sup> Committee on Economic Social and Cultural Rights 'Consideration of report submitted by States Parties under Article 16 and 17 of the Covenant (2008) paragraph 11. UN Doc. No E/C.12/KEN/CO/1, [www2.ohchr.org/english/bodies/cescr/docs/E.C.12.KEN.CO.1\\_EN.pdf](http://www2.ohchr.org/english/bodies/cescr/docs/E.C.12.KEN.CO.1_EN.pdf) (accessed 30 September 2012).

<sup>228</sup> Human Rights Council 'National report submitted in accordance with paragraph 15(a) of the annex to the Human Rights Council resolution 5/1 – Kenya' (3-14 May 2010) paragraph 27. UN Doc. No.: A/HRC/WG.6/8/KEN/1, 9, [www.upr-info.org/IMG/pdf/A\\_HRC\\_WG\\_6\\_8\\_KEN\\_1.pdf](http://www.upr-info.org/IMG/pdf/A_HRC_WG_6_8_KEN_1.pdf) (accessed 30 September 2012).

<sup>229</sup> As above.

<sup>230</sup> P Maybarduk 'ACTA and public health' (2010) 4 PIJIP Research Paper No. 2010-09. American University Washington College of Law, Washington, DC.

<sup>231</sup> UNDP (n 17 above).

with HIV in Kenya only 539,000 people out of 743,000 eligible persons had access to lifesaving ARVs.<sup>232</sup> In light of the above statistics, it is crucial to guarantee access to life-saving generic treatment to sustain lives.<sup>233</sup> The impact of patent on prices of medicines cannot be ignored. Philipe contends that,

[m]edical patents have direct impacts on accessibility and affordability. They have the potential to improve access by providing incentives for the development of new drugs as well as to restrict access because of the comparatively higher prices of patented drugs.<sup>234</sup>

In conclusion, all government policies including under the Anti-Counterfeit Act should focus on the poor and not the rich.<sup>235</sup> As noted by Harrison,

[f]rom a human rights perspective, the most critical issue with many existing assessment is that the impact of trade agreements on the most vulnerable and disadvantaged persons is underexplored or marginalized. The focus of a human rights approach to international trade obligation is primarily to concentrate upon the most vulnerable and disadvantaged in the society. The added value of human rights in this regard is that the impact of trade agreements upon these persons can be measured according to legal obligations entrenched in international legal instruments. But in order to realise this potential, there is need to ensure that those human rights obligations entrenched in international legal instruments have the requisite specificity to be the basis for a real assessment.<sup>236</sup>

### 3.6 Conclusion

Kenya has a positive obligation under the right to health to desist from enacting legislation that will derogate from expeditious and effective implementation of the right to health. One of the core obligations under the right to health is to guarantee access to essential medicines. The socio-economic status of the country makes access to essential generic medicines critical since it is comparatively more affordable than branded medicines.

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<sup>232</sup> As above.

<sup>233</sup> UNAIDS (n 28 above).

<sup>234</sup> P Cullet 'Human rights and intellectual property protection in the TRIPS era' (2007) 29 *Human Rights Quarterly* 416.

<sup>235</sup> As above.

<sup>236</sup> J Harrison & A Goller 'Trade and human rights: What does "impact assessment" have to offer?' (2008) 8(4) *Human Rights Law Review* 603.

## Chapter four

### 4. Implementing the *Patricia Asero case* decision

#### 4.1 Introduction

The main concern of this Chapter is the implementation of the *Patricia Asero* case decision. It discusses the two options available before Parliament, to either repeal the Act or amend it. In this regard, the key concern is to assist the legislature by way of analysis in finding 'a balance between the rules of appropriation and the rules of diffusion in the case of intellectual property rights'.<sup>237</sup> It is crucial that IPRs protection under the Anti-Counterfeit Act not only focus on private rights but also accommodate the legitimate exploitation of lifesaving intellectual goods.<sup>238</sup>

#### 4.2 Two options to implement the *Patricia Asero case* decision

There are only two options available for the legislature to comply with the decision in *Patricia Asero* case. The first option is to repeal the anti-counterfeit legislation. The second option is to amend the anti-counterfeit legislation.

#### 4.3 Repealing the anti-counterfeit legislation

Comparatively, this is an extreme measure. However, it remains an option for the legislature to consider.

One justification is that there currently exist IPRs legislations that could be amended to fill the gaps in IP enforcement.<sup>239</sup> The fact that Kenya is compliant with the TRIPS Agreement by putting in place various legislations including the Industrial Property Act is illustrative of this point.

The next point is that the concept of counterfeiting is not yet fully understood especially with regards to medicines. Kenya and other countries in Africa are being used to unjustly experiment on the appropriate framework since there exists fundamental disagreements

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<sup>237</sup> P Drahos 'Negotiating intellectual property rights: Between coercion and dialogue' (2002) 7 82 *International Intellectual Property Law & Policy* 2.

<sup>238</sup> Spitzlinger, R 'On the idea of owning ideas: Applying Locke's labour appropriation theory to intellectual goods' (2011) 5 *Masaryk University Journal of Law and Technology* 282.

<sup>239</sup> 'The proliferation of anti-counterfeiting legislation in the East African Community: Addressing public health, copyright and developmental concerns' (2010) 7 Report of the international meeting held on 25 – 26 March 2010, Snow Crest Hotel, Arusha, Tanzania, [www.haiafrica.org/index.php?option=com...task..](http://www.haiafrica.org/index.php?option=com...task..) (accessed 26 October 2012).

concerning the normative content of anti-counterfeit legislation at the international level.<sup>240</sup> At the World Health Organization (WHO), more discussions on this issue are ongoing.<sup>241</sup> There appears to be a general consensus amongst scholars on the need for a global anti-counterfeiting treaty to guide anti-counterfeiting efforts. However scholars disagree on the choice of forum with some suggesting that the WHO is best placed to lead the negotiations while others argue in favour of the United Nation Office on Drugs and Crimes (UNDOC).<sup>242</sup>

Lastly, there appears to be some confusion about the approach of the Kenya anti-counterfeiting legislation with the High Court observing that it places IPRs protection before consumer protection and the government stating that it was meant to safeguard public interest and specifically consumers from the adverse effects of counterfeiting and ensure that medicines on market are of the required standards.<sup>243</sup> The government's submission with regard to the intention of the act is problematic. First, the Anti-Counterfeiting Act as observed by the High Court fails to safeguard consumers but instead protect IPRs.

The above reasons and others may be used to justify a complete repeal of the anti-counterfeiting legislation in Kenya.

#### **4.4 Amending the anti-counterfeiting legislation**

This appears to be the route chosen by the government. Available information confirms that amendments of the anti-counterfeit legislation have been drafted and will be tabled soon for appropriate intervention by stakeholders.<sup>244</sup> The main concern however remains the role of US in the anti-counterfeiting agenda in the region. Already, there are plans to push the 'IPRs enforcement agenda forward by linking it to quality and safety issues as well as to claims of the devastating effects on the economy and FDI (foreign direct investment)'.<sup>245</sup> The US Department of Commerce's Commercial Law Development Program (CLDP) has already conducted various

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<sup>240</sup> See discussions around the Anti-Counterfeiting Trade Agreement (ACTA).

<sup>241</sup> In 2006, the WHO created the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) to examine, *inter alia*, the role of WHO in prevention and control of substandard/spurious/false-labelled/falsified/counterfeit medical products.

<sup>242</sup> For a complete debate on this issue see A Attaran, R Bate & M Kendall 'Why and how to make an international crime of medicine counterfeiting' 9 *Journal of International Criminal Justice* (2011), 325-354; N Coister & B McGrady 'Why and how to make a treaty crime of medicine counterfeiting; A reply to Attaran, Bate and Kendall' (2011) 9 *Journal of International Criminal Justice* 947-951; A Attaran, R & M Kendall 'A response to the comments by boister and McGrady' (2011) 9 *Journal of International Criminal Justice* 953-957

<sup>243</sup> See paras 42 & 83 of the *PATRICIA ASERO*. decision.

<sup>244</sup> Email from Anonymous, global access to medicines advocate, on 30 July 2012.

<sup>245</sup> Email from Anonymous, global access to medicines advocate, on 8 August 2012.

meeting with African countries to push for 'TRIPS plus e.g. for patent linkage and other TRIPS plus provisions to be implemented.'<sup>246</sup>

The process of amendment may prove very difficult due to the existence of foreign interests which are pushing for patent linkages and also for other TRIPS plus measures at the expense of developing countries interests including access to essential medicines.

#### **4.5 Overview of the 'Musungu framework' principles for addressing public health concerns in anti-counterfeit laws<sup>247</sup>**

Musungu, one of the leading experts in Kenya on anti-counterfeiting and public health, has proposed a framework, the 'Musungu framework', concentrating on six key areas that should be taken into account in order to safeguard access to essential medicines including generics in anti-counterfeit laws. These six areas are summarised in this study as follows: definition of counterfeiting; criminal liability for counterfeiting offences; powers of seizures and storage; goods in transit; rules of evidence; and liability for unwarranted detention, loss of or damage to goods.

##### **4.5.1 Definition of counterfeiting<sup>248</sup>**

The 'Musungu framework' notes that there are three problems in this area. The first problem is with regard to an internationally acceptable definition as was discussed previously in this Chapter. According to Musungu, the definition of counterfeiting that is internationally acceptable is that contained in the TRIPS Agreement definition. There also exists a need to distinguish between Criminal and civil liability for counterfeiting since Article 61 of the TRIPS Agreement limits counterfeiting warranting criminal sanctions to wilful trademark infringement on commercial scale. Therefore, using 'counterfeiting' definition in the context of patent rights infringement is beyond the definition under the TRIPS Agreement. The second problem is that broad definitions would most likely infringe on human rights including the right to health. The third and final problem is that there exists suspicion about the intention of IP enforcement advocates when they propose wide definitions in anti-counterfeit laws. Skeptics see it as an attempt to frustrate trade in generic medicines and not an issue of public safety or consumer

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<sup>246</sup> As above.

<sup>247</sup> This part is adapted from UNDP (n 17 above), 17 - 31.

<sup>248</sup> As above, 17 - 19.

protection as often claimed by proponents of anti-counterfeiting legislations. To deal with the above limitations, Musungu proposes the following legislative principles:<sup>249</sup>

- The definition of 'counterfeiting' should be limited to wilful criminal trademark counterfeiting on a commercial scale as defined in the TRIPS Agreement.
- If the law also covers copyright infringement, 'piracy' should be defined separately, also based on the TRIPS definition.
- Civil trademark infringement/confusion and patents should not be included in the scope of any definition of 'counterfeiting'.

#### **4.5.2 Criminal liability for counterfeiting offences<sup>250</sup>**

There are also three reasons against criminalization of 'counterfeiting' as codified under article 61 of the TRIPS Agreement. First and foremost, there is no obligation under the TRIPS Agreement to criminalize patent infringement and civil trademark infringement other than for wilful trademark and copyright infringements on a commercial scale. Secondly, criminalization cannot be justified unless it is 'intended to confuse consumers and distort informed trade'. The third reason against criminalization is the proportionality principle under criminal law. Accordingly, article 61 of the TRIPS Agreement stipulates that criminal sanctions for IPRs infringement must be proportional to other domestic punishments for similar crimes. In this regard, the following legislative principles have been proposed:<sup>251</sup>

- For a criminal liability to attach to an act of trademark counterfeiting, such an act must be proven to be wilful and on a commercial scale (as defined by the WTO panel in the USA-China case).
- The penalties imposed for counterfeiting must be proportional to the offence committed.
- Offences and penalties should be put in place to ensure procedures under 'anti-counterfeiting' laws are not abused and that they are applied fairly, equitably and for the intended purpose.

#### **4.5.3 Powers of seizures and storage<sup>252</sup>**

For powers of seizures, the 'Musungu framework' urges the adoption of judicial review procedures to mitigate on the potential adverse effects that may result if these powers are

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<sup>249</sup> As above 19.

<sup>250</sup> As above, 20 – 22.

<sup>251</sup> As above, 21.

<sup>252</sup> As above, 23 – 24.

misused or abused. On the other hand, with regard to storage, the concern is that medicines require special conditions of storage including the right temperature. Poor storage, therefore, may lead to good quality medicines being sub-standard because of contamination or other effects. Under ideal circumstances, storage should be avoided for good quality drugs and instead civil claims should be encouraged to recover loss of profits and/or damages. The following principles are proposed:<sup>253</sup>

- In a free and democratic society, granting and exercising powers by governmental agencies with respect to private property must conform to human rights standards, proper administration of justice and constitutional safeguards.
- Powers to seize or otherwise interfere with private property must be conditioned upon judicial oversight by way of a warrant system.
- The powers granted to governmental agencies and officials must not provide incentives or opportunities for corruption.
- These powers should be proportional and equipped with strong safeguards against their abuse.
- Goods seized under anti-counterfeit laws need to be stored in a manner that ensures that they are not contaminated and that their quality and safety are not otherwise compromised.

#### **4.5.4 Goods in transit<sup>254</sup>**

The focus on goods in transit provision was prompted by the adverse impact of European Council's (EC's) Council Regulation 1383/2003 which has seen the period 2008 and 2009 German customs officials detaining nearly 20 shipments. Both Article V of the General Agreement on Trade and Tariffs (GATT) and Article 41.1 of the TRIPS Agreement condemn in their texts non-tariff barriers to free trade. Musungu argues that when seizures of in-transit-medicines happen, reliance is on 'manufacturing fiction' argument which is contrary to the TRIPS Agreement that 'IP status of suspected goods be assessed based on the IP status of the goods in the destination (import) country rather than the transit country. The following two legislative principles are therefore proposed:

- Anti-counterfeit procedures and measures should not become barriers to legitimate international trade.

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<sup>253</sup> As above, 24.

<sup>254</sup> As above 25 – 28.



- Anti-counterfeiting procedures and measures should conform to the obligations of the country under WTO rules, including the GATSS rules on freedom of transit.

#### **4.5.5 Rules of evidence<sup>255</sup>**

A new problematic trend with regard to proving ownership of IP right or interest has been developed under the current anti-counterfeiting legislations. A presumption of ownership is made for IP rights ownership for complainants until proven otherwise. This shift of the burden of proof is not desirable since it may impede legitimate trade as well as the rights of the defendant. The key principle to be applied in this case is that 'whoever alleges interference with their right must first prove that they own or are entitled to such right'.<sup>256</sup>

#### **4.5.6 Liability for unwarranted detention, loss of or damage to goods<sup>257</sup>**

The position here is that any wrongful seizure, removal or detention of goods made in bad faith, negligently or through false information must be borne by the government and the complainant who initiates 'wrongful or unsuccessful IP enforcement application and procedures'. There are two principles that should guide in this regard are as follows:<sup>258</sup>

- Any owner or holder of goods who suffers loss due to the wrongful seizure, removal or detention of their legitimate goods should be compensated.
- Consumers should not be deprived of access to legitimate essential goods, such as medicines, for any reason, and should be compensated for harm proximately caused by wrongful or ultimately unsuccessful IP enforcement activities.

### **4.6 Model amendments to the Kenyan anti-counterfeit legislation**

Applying some of above principles discussed above, the following model proposed amendments are proposed to the Kenyan Anti-Counterfeit Act to safeguard access to essential medicines including generic medicines.

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<sup>255</sup> As above, 29.

<sup>256</sup> As above.

<sup>257</sup> As above, 30 – 31.

<sup>258</sup> As above, 31.

TEXT AS IT APPEARS ON THE LEGISLATION	THE PROPOSED AMENDMENT(S) TEXT	SPECIFIC ACTION(S) TO BE TAKEN BY THE LEGISLATURE	FURTHER EXPLANATION
<b>SECTION 2 – INTERPRETATION</b>			
<p>“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-</p> <p>(a) the manufacture, production, packaging, re-packaging, labelling 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;</p> <p>(b) the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, 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</p>	<p>“counterfeiting” means taking the following actions, wilfully and on a commercial scale, without the authority of the owner of intellectual property rights subsisting in Kenya in respect of protected goods-</p> <p>(a) the manufacture, production, packaging, re-packaging, labelling 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;</p>	<p>Add ‘wilfully and on a commercial scale</p> <p>Delete ‘or elsewhere’</p> <p>Delete paragraph (b) and (d).</p>	<p>The principle of proportionality requires that criminal sanctions are proportional to the offence committed. As such, only counterfeiting offence committed wilfully and on a commercial scale qualifies for protection under this Act.<sup>259</sup></p> <p>Intellectual property rights apply territorially and not extra-territorially<sup>260</sup>.</p> <p>The categories of “counterfeiting” should be restricted to ‘trademark infringements’ and ‘pirated-copyrights’ in line with Kenya’s obligations under the TRIPS Agreement.</p>

<sup>259</sup> See also Article 61(1) of the TRIPS Agreement that provides for criminal sanctions for willfull trademark counterfeiting and pirated copyrights on a commercial scale.

<sup>260</sup> See also section 2 of the Ugandan Anti-Counterfeit Bill, 2009. It limits ‘counterfeiting’ to infringement of trademarks or piracy of copyrights in Uganda in respect of protected goods.

<p>manufactured, produced or made under his licence;</p> <p>(c) the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author's rights or related rights;</p> <p>(d) in relation to medicine, the deliberate and fraudulent mislabelling 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;</p> <p>Provided that nothing in this paragraph shall derogate from the existing provisions under the Industrial Property Act.</p>	<p>(b) the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author's rights or related rights;</p>	<p>Delete the entire proviso</p>	<p>There is no additional import for providing a separate definition for medicines having severed patents from the application of this Act.</p> <p>The proviso under this section is vestigial and serves no purpose at all.<sup>261</sup></p>
<p>"counterfeit goods" means goods that are the result of counterfeiting, and includes any means used for purposes of counterfeiting;</p>	<p>"Counterfeit goods" means goods that are the result of counterfeiting;</p>	<p>Delete 'and includes any means used for purposes of counterfeiting'.</p>	<p>"Counterfeit goods" refers to physical commodities and, therefore, including "means used" is beyond the scope of this definition.<sup>262</sup> This may also put into jeopardy access to active pharmaceutical</p>

<sup>261</sup> This point was made by the Presiding Judge Justice Mumbi Ngugi while delivering the Judgment of *PATRICIA ASERO* case. She noted that 'the Anti-Counterfeit Act, being later in time, would prevail over the Industrial Property Act in the case of a conflict, and the proviso to section 2 may not be of much help to the petitioners.'

<sup>262</sup> See also section 2 of the Ugandan Anti-Counterfeit Bill 2010, which limits counterfeit goods to infringements of copyrights and trademarks.

			ingredients (API) and other innocent third parties. <sup>263</sup>
<p>"intellectual property right" includes–</p> <p>(a) any right protected under <u>the Copyright Act</u>;</p> <p>(b) any plant breeders' right granted under the Seeds and Plant Varieties Act;</p> <p>(c) any right protected under <u>the Trade Marks Act</u>; and</p> <p>(d) any right protected under <u>the Industrial Property Act</u>;</p>	<p>"intellectual property right" means–</p> <p>(a) any right protected under <u>the Copyright Act</u>; and</p> <p>(c) any right protected under <u>the Trade Marks Act</u>;</p>	<p>Delete paragraph (b) and (d)</p>	<p>Intellectual property rights in the context of counterfeiting are applicable to rights granted under trademark laws and/or copyright laws.<sup>264</sup></p>
<p>"protected goods" means–</p> <p>(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;</p> <p>(b) any particular class or kind of goods which, in law, may feature, bear,</p>	<p>"protected goods" means–</p> <p>(a) goods featuring, bearing, embodying or incorporating the subject matter of an intellectual property right;</p> <p>(b) any particular class or kind of goods which, in law, may</p>	<p>Delete '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;'</p> <p>Delete 'only with the authority of the owner of that intellectual property right, or to which that</p>	<p>The definition of "protected goods" should not be ambiguous and IPRs protection must be in Kenya.<sup>265</sup></p>

<sup>263</sup> For more on this see BK Baker 'ACTA: Risk of Third-Party Enforcement for access to medicines' *PIJIP Research Paper No. 2010-01*.

<sup>264</sup> See also section 2 of the Ugandan Anti-Counterfeit Bill 2010, which interprets 'intellectual property' under the legislation to mean trademarks and copyrights in Uganda in respect of protected goods. However, The East African Community Anti-Counterfeit Bill of 2010 includes Plant Breeder's rights as a category of intellectual property rights under the legislation. It however fails to include patents.

<sup>265</sup> It is in the interest of law enforcement officers and all actors to have clarity on the subject matter of what constitutes 'protected goods'. In this regard, Kenya should not recognise protection outside its territories since this will have significant implication on access to essential medicines.

<p>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;</p>	<p>feature, bear, embody or incorporate the subject matter of an intellectual property right;</p>	<p>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;'</p>	
<p>"intellectual property right" includes—</p> <p>(a) any right protected under <u>the Copyright Act</u>;</p> <p>(b) any plant breeders' right granted under the Seeds and Plant Varieties Act;</p> <p>(c) any right protected under <u>the Trade Marks Act</u>; and</p> <p>(d) any right protected under <u>the Industrial Property Act</u>;</p>	<p>"intellectual property rights" includes-</p> <p>(a) Any right protected under the Copyright Act; and</p> <p>(b) Any right protected under the Trade Marks Act.</p>	<p>Delete paragraph (b) and (d)</p>	<p>The scope of intellectual property should be limited to rights granted under trademarks and copyrights<sup>266</sup></p>

<sup>266</sup> The TRIPS Agreement limits counterfeiting to 'trademark infringement' and 'pirated copyrights'.

<b>Part IV – Inspection</b>			
<b>Section 22 – Appointment of Inspectors</b>			
<p>(1) The Board shall, for purposes of enforcing the provisions of this Act, appoint such number of inspectors as the Board may consider appropriate and shall issue to them, in writing or in such form as may be prescribed, certificates of authority to act as inspectors.</p> <p>(2) A person appointed as an inspector under subsection (1) shall—</p> <p>(a) hold office subject to such terms and conditions as the Board may determine;</p> <p>(b) have full police powers in the exercise of their duties under this Act</p> <p>(3) In addition to inspectors appointed under subsection (1), any member of the Board, police officer, authorised customs officer, trade development officer, industrial development officer, trade mark and patent examiner, seed and plant inspector, public health inspector, and inspectors appointed under the Standards Act, the Weights and Measures Act, the <u>Copyright Act</u>, the Food,</p>	<p>(1) The Board shall, for purposes of enforcing the provisions of this Act, appoint such number of inspectors as the Board may consider appropriate and shall issue to them, in writing or in such form as may be prescribed, certificates of authority to act as inspectors.</p> <p>(2) A person appointed as an inspector under subsection (1) shall—</p> <p>(a) hold office subject to such terms and conditions as the Board may determine;</p> <p>(b) have full police powers in the exercise of their duties under this Act</p> <p>(3) In addition to inspectors appointed under subsection (1), any member of the Board, police officer, authorised customs officer, trade development officer, industrial development officer, trade mark and patent examiner, seed and plant inspector, public health inspector, and inspectors appointed under the Standards Act, the Weights and Measures Act, the <u>Copyright Act</u>, the Food,</p>	<p>Add paragraph '(7) Notwithstanding subsection (1), (2), (3), (4) and (5), in relation to medicines, only inspectors appointed under the Pharmacy and Poisons Act shall act as inspectors under this Act.'</p>	<p>There is need to separate the enforcement of counterfeit medicines from other commodities because of the complexity of medicine products and the need to safeguard their access.<sup>267</sup></p>

<sup>267</sup> Contrast this with the miscellaneous provisions under section of the Ugandan Anti-Counterfeit Act. It provides that 'medicines shall be dealt with by the National Drug Regulatory Authority under the National Drug Policy and Authority Act.' The proposal in this part however is for a collaborative approach that maximizes the synergies between the two institutions as opposed to complete severance. This is justifiable particularly with regards to international crime aspects of counterfeiting that may be beyond the capacity of a national drug authority to combat.

<p>Drugs and Chemical Substances Act, the Pharmacy and Poisons Act and the Pest Control Products Act are hereby designated as inspectors for purposes of this Act.</p> <p>(4) The Board may designate other public officers to be inspectors for purposes of this Act.</p> <p>(5) The Board may amend or withdraw appointment of inspectors or designated inspectors under this section.</p> <p>(6) Appointment of inspectors under this section shall be by notice in the Gazette.</p>	<p>Drugs and Chemical Substances Act, the Pharmacy and Poisons Act and the Pest Control Products Act are hereby designated as inspectors for purposes of this Act.</p> <p>(4) The Board may designate other public officers to be inspectors for purposes of this Act.</p> <p>(5) The Board may amend or withdraw appointment of inspectors or designated inspectors under this section.</p> <p>(6) Appointment of inspectors under this section shall be by notice in the Gazette.</p> <p>(7) Notwithstanding subsection (1), (2), (3), (4) and (5), in relation to medicines, only inspectors appointed under the Pharmacy and Poisons Act shall act as inspectors under this Act.</p>		
<p><b>32.</b> It shall be an offence for any person to—</p> <p>(a) have in his possession or control in the course of trade, any counterfeit goods;</p> <p>(b) manufacture, produce or make in the course of trade, any counterfeit goods;</p> <p>(c) sell, hire out, barter or exchange, or offer or expose for sale, hiring out, barter or exchange any counterfeit goods;</p> <p>(d) expose or exhibit</p>	<p>32. It shall be an offence for any person to—</p> <p>(a) have in his possession or control in the course of trade, any counterfeit goods;</p> <p>(b) manufacture, produce or make in the course of trade, any counterfeit goods;</p> <p>(c) sell, hire out, barter or exchange, or offer or expose for sale, hiring out, barter or exchange any counterfeit goods;</p>	<p>Delete 'transit through' under paragraph f.</p>	<p>It may be very hard for Kenya to ascertain whether a product is counterfeit or not if it is transiting through the country. This is because IPRs protection is a territorial issue. Similarly, in-transit measures is contrary to the spirit of GATT and WTO on non-tariff barriers to trade.</p>

<p>for the purposes of trade any counterfeit goods;</p> <p>(e) distribute counterfeit goods for purposes of trade or any other purpose;</p> <p>(f) import into, transit through, tranship within or export from Kenya, except for private and domestic use of the importer or exporter as the case may be, any counterfeit goods;</p> <p>(g) in any other manner, dispose of any counterfeit goods in the course of trade.</p>	<p>(d) expose or exhibit for the purposes of trade any counterfeit goods;</p> <p>(e) distribute counterfeit goods for purposes of trade or any other purpose;</p> <p>(f) import into, tranship within or export from Kenya, except for private and domestic use of the importer or exporter as the case may be, any counterfeit goods;</p> <p>(g) in any other manner, dispose of any counterfeit goods in the course of trade.</p>		
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## 4.7 Some challenges

As emphasized in this study, the implementation of the above amendments will not come easy. This study identifies five challenges that may ensue in the process of pushing for amendments, namely: External influence and threats; delayal tactics and propaganda; human rights versus trade language barrier; mass mobilisation of stakeholders; and accommodating competing inter-agency interests.

### 4.7.1 External influence and threats

This is perhaps the most difficult challenge because of the importance of IPRs protection and enforcement to external actors especially developed nations. Because these countries regard IPRs as a major component of their export they will fight hard to ensure that stronger protection is awarded. This may include threats and trade sanctions. Stakeholders must prepare to counter external influence and threats by naming and shaming countries that stand against access to essential medicines.

### 4.7.2 Delayal tactics and propaganda

Because of lack of an internationally accepted normative framework on anti-counterfeiting and public health, and the nature of the competing interests, trade and human rights, delay is



expected. The two groups may engage in a long and protracted war concerning norms and their implementation. Both sides should prepare adequately in terms of resources to engage in the process to the very end. Parliament appears to be the greatest hurdle and appropriate strategies should be devised to prepare them adequately. Propaganda may be employed to turn the public against pro-human rights demands.

#### **4.7.3 Human rights versus trade language barrier**

During the hearing of the *Patricia Asero* case, it was evident that the trade language differs considerably to the human rights language. For trade actors, their interests are to promote trade and investments and for human rights actors their interests are to guarantee access and human welfare. This may lead to a language barrier if not approached properly.

#### **4.7.4 Mass mobilisation**

In order to lobby successfully for favourable amendments the support of the community must be sought after and secured. The challenge foreseeable is engaging the community in discussing the technical issues that are involved in this case. Sufficient training must be done to target communities especially persons living with HIV in order to mitigate this challenge.

#### **4.7.5 Accommodating competing inter-agency interests**

While proposing for the inspectors of drugs appointed under the Pharmacy and Poisons Act may be desirable for safeguarding access to essential medicines, competition from inspectors appointed under the Anti-Counterfeiting Act may present a major challenge. This should be avoided by emphasizing on synergies between the two agencies.

### **4.8 Conclusion**

The main approach of the proposed amendments to safeguard access to essential medicines is to first and foremost sever patent linkage in the Anti-Counterfeit Act. This could be achieved by restricting the scope 'counterfeiting' definition to 'trademark infringement' and 'pirated copyright' in line with the TRIPS Agreement. Secondly, with regard to medicines, provide for inspector of drugs appointed under the Pharmacy and Poisons Act<sup>268</sup> to enforce the Anti-Counterfeit Act.

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<sup>268</sup> Chapter 244 Laws of Kenya.

## CHAPTER FIVE

### 5. Summary of the Chapters, conclusions and recommendations

This Chapter discusses the summary of the previous Chapters, conclusions and recommendations of this study.

#### 5.1 Summary of Chapters

There are a total of five Chapters in this study. The discussions in the four substantive Chapters are summarised below.

##### 5.1.1 Summary of Chapter one

This Chapter introduces the study. It underscores the fact that the TRIPS Agreement marked the beginning of the globalisation of IPRs protection. This was followed by efforts to ratchet IPRs protection in exchange of market access in developed countries. A good manifestation of this process is the Kenya Anti-Counterfeit Act which was enacted in 2008 to combat counterfeiting trade. However, it was met by strong opposition from various sectors including, the global access to medicines group because of its over-broad provisions extending beyond the TRIPS Agreement. In 2009, three petitioners living positively with HIV approached the High Court and sought orders to declare the legislation unconstitutional insofar as it restricted access to essential medicines. The main point of contention, according to the petition, was article 2 of the Anti-Counterfeit Act which defined 'counterfeiting' to include patent linkage. This potentially jeopardizes access to generic drugs. The chapter also discusses available literature and theory of this study amongst other things.

##### 5.1.2 Summary of Chapter two

From the analysis of the *Patricia Asero* case, this Chapter discusses section 2 of the Anti-Counterfeit Act. It notes that patent linkage remains the main concern in respect to access to essential medicines in the Act. The implications of this case including saving lives in Kenya and beyond were also explored in details. In the author's view, the decision will be praised for many years to come because of the fact that, if implemented, many lives dependant on essential medicines will be saved.

##### 5.1.3 Summary of Chapter three

In this chapter, the author showed that Kenya has obligations at the national, regional, and international levels to implement the right to health. With regard to socio-economic imperatives,

the study noted that the majority of Kenyans were poor and dependent on generics. Therefore, the Anti-Counterfeit Act insofar as it restricts its access is unconstitutional and violates the right to health.

#### **5.1.4 Summary of Chapter four**

This Chapter tackled the implementation of the *Patricia Asero* case decision. This Chapter offers a tool, in form of model amendments for engagement in the process of amending the bad provisions of the Anti-Counterfeit Act. The priority is to delink patent protection from the scope of the Anti-Counterfeit Act and bestow upon inspectors of drugs appointed under the Pharmacy and Poisons Act the powers to take charge with respect to medicine products. This approach draws on the 'Musungu framework' principles for safeguarding public health and access to essential medicines in anti-counterfeit legislations.

#### **5.2 Conclusions**

The following are the conclusions of this study:

- a. The Kenya Anti-Counterfeit Act, as currently enacted, contains provisions that, if applied, would adversely impact access to essential generic medicines in Kenya. The main concern is the definition of 'counterfeiting' under the Act which includes patent protection. The inclusion of patents makes legitimately produced generic medicines liable for confiscation under the Act.
- b. The enactment of the Kenya Anti-Counterfeit Act constitutes, *ipso facto*, derogation by Kenya from its obligations to promote and protect the right to health. The right to health is provided for under the Kenyan Constitution as well as regional and international instruments. The right entails both negative obligations as well as positive obligations. Enacting a legislation that restricts access to medicines constitute a violation of the positive obligation under the right to health. To the extent that the medicines restricted are essential, the Act violates a non-derogable core obligation and must be rescinded.
- c. The decision against the Kenya Anti-Counterfeit Act offers a unique opportunity for the government to re-look at the Act and through a participatory process in order to safeguard access to essential generic medicines in Kenya. In order to achieve this, the Act must delink patent protection from the application of the Act. Secondly, the enforcement of the Act with regard to medicines must be undertaken by inspector of

drugs appointed under the Pharmacy and Poisons Act. The two measures would constitute sufficient safeguards to access to essential medicines.

- d. The main challenge against this process remains external influence from stakeholders who have vowed and are working hard to ensure that patent linkages and other TRIPS plus measures remain in the Kenya Anti-Counterfeit Act. Leading this interest group is the US that has been sponsoring enforcement meetings all over Africa. They have also been pushing for patent linkages and other TRIPS plus measures to be included in anti-counterfeit legislations.
- e. There exists a strength that cannot be overwhelmed when all stakeholders are adequately engaged in a common purpose as was in the *Patricia Asero* case. In the *Patricia Asero* case, apart from the three petitioners, there were also AIDS Law project (ALP), a local non-governmental organisation (NGO), and the *amicus*, the UN Special Rapporteur. The court audience were persons living with HIV and AIDS and other actors including international media that covered the case. Such cooperation raised the profile of the case. It may have also contributed to the decision of the government not to appeal the case.

### 5.3 Recommendations

The recommendations of this study are as follows:

The government

- a. The government must lead other stakeholders in amending the Kenya Anti-Counterfeit Act expeditiously. As noted above, the Act endangers access to legitimate generic drugs. In this regard, in order to provide for sufficient safeguards under the Act to guarantee access to essential generic drugs, the Act should not provide for patent protection. Secondly, the enforcement of the Act with regard to medicines should be delegated to inspector of drugs appointed under the Pharmacy and Poisons Act.
- b. The government should resist external pressure to maintain patent linkages and other TRIPS plus measures in the Kenya Anti-Counterfeit Act. In particular, the government must listen to all stakeholders while giving concessions in the area of IPRs. This will ensure that no concession with adverse effects will be given. Secondly, during enforcement trainings, the government must guarantee a balanced programme to

ventilate on all issues adequately and build the capacity of enforcement officers in an objective manner.

- c. The government must observe its obligations under the Constitution, domestic legislation, regional and international instruments especially with regard to health. Under this right, the government is obliged to act expeditiously and effectively to guarantee its realisation. Derogation is generally prohibited with limited exceptions which must be qualified taking into account utilisation of all available resources. The right to health, the right to life and the right to human dignity are inextricably linked.
- d. The government must build the capacity of its officers to handle IPRs negotiations in a manner that would benefit the country. It is clear that during trade negotiations, Kenya conceded much on very critical issues revealing a critical gap in terms of capacity. In this regard, the World Intellectual Property Organisation (WIPO) must provide unbiased technical assistance to developing countries to protect them from exploitation by their often powerful opponents. The government must also utilise fully its flexibilities once secured to intervene in various situations including public health emergency.

#### Global access to medicines actors

- e. Provide support to the government in form of research and mass mobilisation to reject TRIPS plus measures in Kenya's IPRs landscape. The Kenyan *Patricia Asero case* benefitted directly from years of research from global access to medicines actors. If credible research had been unavailable, it would have been difficult to prove the implications of the Kenya Anti-Counterfeit Act on public health for example. Research findings must also be disseminated to enforcement officers in form of regular trainings or publication.
- f. In order to achieve expeditious policy reforms to roll back TRIPS plus measures in domestic legislations including in the Anti-Counterfeit legislation the public must be involved in pressuring the government.
- g. Monitor closely and report on a regular basis on the process of amending the Kenya Anti-Counterfeit Act in order to secure access to essential medicines interests. Reports from government indicate that the government has already prepared the necessary

amendments which will be ready for discussions soon.<sup>269</sup> Once released, the amendments must be thoroughly vetted and any gap filled. The model amendments generated in this study may offer critical tool in evaluating the adequacy of the amendments to safeguard access to essential medicines.

- h. At the international level, a strong lobby team should be formed to provide support to developing countries in pushing for the inclusion of development concerns in IPRs treaties. This will counterbalance the already strong trade lobby groups pushing for stronger IPRs protection globally.

WORD COUNT 19 958 (including footnotes but excluding table of contents and bibliography)

- END -

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<sup>269</sup> At the time of submitting this study, I had not received any specific date the amendments would be made public.

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