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# Effective anti-counterfeiting legal system: a key enabler for growth of Kenya's pharmaceutical industry

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**Effective Anti-Counterfeiting Legal System: A Key Enabler for Growth of Kenya's  
Pharmaceutical Industry**

**Lusi, Wilfred Ogot**

**Submitted in part-fulfilment of the requirements for the Degree of Master of Laws  
Strathmore University, Strathmore Law School**



**June, 2020**

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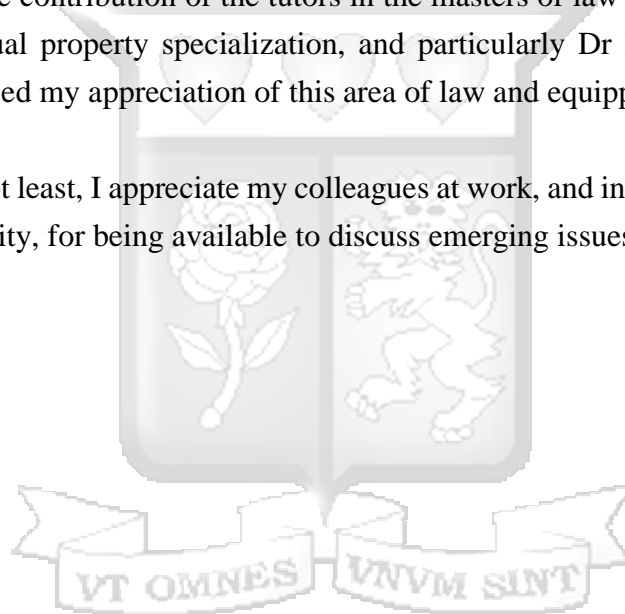
## ACKNOWLEDGEMENTS

In enrolling for this post-graduate degree specializing in intellectual property law, my desire was not just to increase my appreciation of this fairly nascent area of law (in Kenya); but to better equip me in supporting the enforcement of intellectual property rights, particularly for my clients and also contribute to the national efforts to better protect intellectual property rights. I therefore thank the almighty God for seeing me through the rather rigorous training at the Strathmore University School of law – a most demanding but pleasantly rewarding experience.

I acknowledge the guidance of my supervisor Dr Isaac Rutenberg, who guided the conduct and finalization of this study through invaluable academic contribution, positive critique and direction.

I also acknowledge the contribution of the tutors in the masters of law program generally and those in the intellectual property specialization, and particularly Dr Peter Munyi, for their tutelage which enhanced my appreciation of this area of law and equipped me for this study.

Lastly but certainly not least, I appreciate my colleagues at work, and in the LLM pioneer class at Strathmore University, for being available to discuss emerging issues and for travelling this path together.

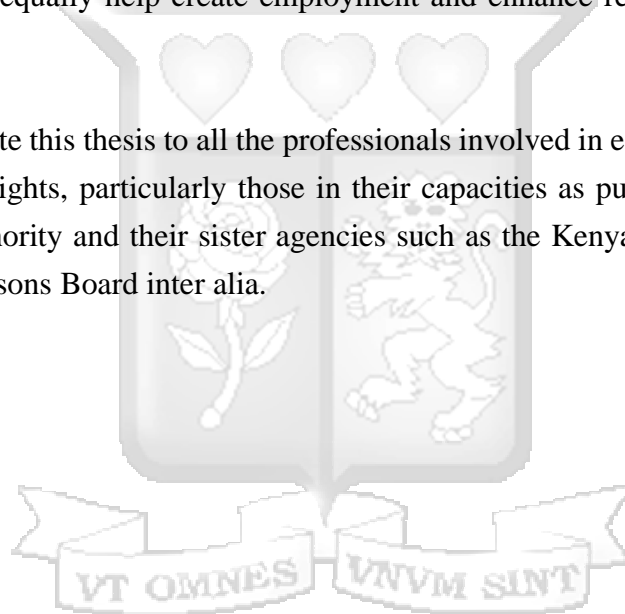


## DEDICATION

I dedicate this work to my Queen #Wagusudarling, my beautiful princesses #Lera and #Zindi as well as my entire family for their sacrifice, support and encouragement during the conduct of this study.

This research project aims at informing apt reform in the approach adopted by Kenya, to effectively enforce the protection accorded to intellectual property rights in the pharmaceutical industry. This is in recognition, not only, of the need to better guarantee the attainment of quality and affordable healthcare for all; but also, the need to ensure that the innovators and/or investors within the pharma-sector receive *commensurate* returns for their innovation and investments. Striking the right balance in these oft competing interests, necessarily incentivizes the effort to grant and guarantee protection of intellectual property rights within the pharma-sector. It is this paper's finding that apt enforcement of intellectual property rights within the pharma industry will equally help create employment and enhance revenue for government through licit trade.

I therefore also dedicate this thesis to all the professionals involved in enforcement of pharma-intellectual property rights, particularly those in their capacities as public officers under the Anti-Counterfeit Authority and their sister agencies such as the Kenya Bureau of Standards, the Pharmacy and Poisons Board inter alia.



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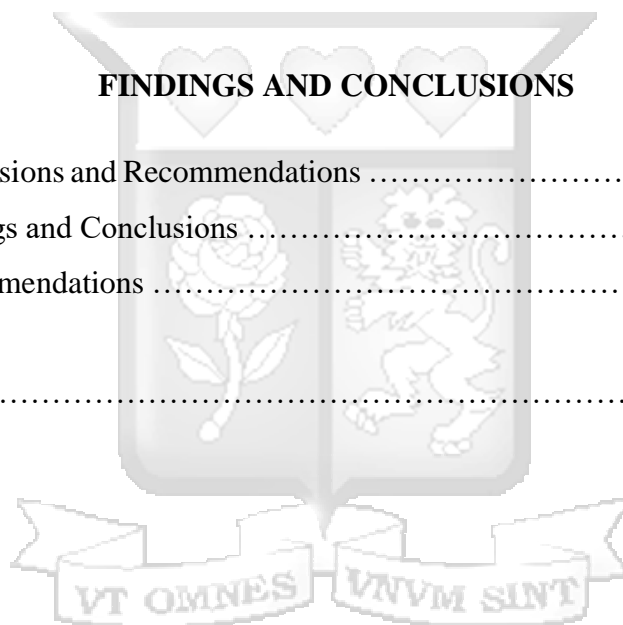
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## 1.0 Chapter One – Introduction

### 1.1 Background and Introduction

Michael Blakeney describes *counterfeits* as “goods, manufactured, distributed and sold as copies of goods which have been made without the authority of the owner of the intellectual property.”<sup>1</sup> These goods – he notes - are intended to appear so similar to the original, so as to be *passed off* as genuine items. According to Ben Sihanya counterfeiting is the use of intellectual property rights (IPRs) without authority to produce similar or substantially identical product to legitimate products.<sup>2</sup> This often includes use of famous brand-names, on pharmaceutical products (pharma-products) not manufactured by or on behalf of the owner of the trade mark, as well as exact copies which are traded in a form intended to be indistinguishable from the genuine pharma-product. He argues that counterfeiting connotes wilful infringement of IPRs and involves elements of fraud, forgery and deception variously consumers and legitimate traders reposing counterfeiting within realm of criminal law.<sup>3</sup>

Blakeney’s definition makes it imperative to demystify the term *Intellectual Property Rights* as a preliminary in this study. It also constrains an exposition of what constitutes an Intellectual Property (IP) system and the entitlements conferred upon an IPR owner. Significantly, Blakeney’s and Sihanya’s definition appears to circumscribe ‘*counterfeit-ability*’ to defined IPR relating to ‘*product-identification*’.

Harvard Law’s William Fisher conceives IPRs as “a loose cluster of legal doctrines that regulate the uses of different sorts of ideas and insignia. The law of copyright protects various ‘original forms of expression,’ including novels, movies, musical compositions, and computer software programs. Patent law protects inventions and some kinds of discoveries. Trademark law protects words and symbols that identify for consumers the goods and services manufactured or supplied by particular persons or firms. Trade-secret law protects commercially valuable information (soft-drink formulas, confidential marketing strategies etc) that companies attempt to conceal from their competitors. The “right of publicity” protects celebrities’ interests in their images and identities.”<sup>4</sup> From Fisher’s definition it is apparent that within the various classes of IPRs, it is Trademark and copyright law that best co-hear with Blakeney’s and Sihanya’s conceptualisation of counterfeits-proper.

The definition of IPRs by Fisher importantly elicits the numerous taxonomies of IPRs, within the larger understanding of the heterogeneous body of rights, collectively defined as, IPRs. These body of rights create defined exclusive legal entitlements (in the nature of proprietary

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<sup>1</sup>Blakeney M, ‘*Counterfeiting and Piracy: An Overview*’ in International Chamber of Commerce, Counter-Intelligence Bureau, The International Anti-Counterfeiting Directory, 2005, 9.

<sup>2</sup>Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa, Transferring Technology for Development*, Sihanya Mentoring & Innovative Lawyering, Nairobi, 2016, 455.

<sup>3</sup>Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 492.

<sup>4</sup> Fisher W, Theories of Intellectual Property, <http://www.law.harvard.edu/faculty/tfisher/iptheory.html>.

rights) to the particular creation, expression, innovation or invention. The IPRs subsist under an IP regime comprising of an inter-linked tri-limb, *first* creation (which includes termination and effluxion of rights); *secondly* exploitation (which includes administration, management and commercialisation of rights); and *lastly*, enforcement (civil and criminal) of the IPRs. This study addresses itself to the last of these three (3) limbs, i.e. what is the effectiveness of Kenya's anti-counterfeiting legal system; and the effect thereof on growth of Kenya's pharma-industry.

IPRs and the wholesome IP regime are undoubtedly of great significance in economic advancement, the world over and especially in developing economies like Kenya. Sihanya highlights that most developing nations ironically do not regard IP enforcement as a key strategic issue for sustainable development; vis-à-vis issues such as health, security, employment and wealth creation whereas effective IP enforcement is actually a key enabler for attaining this other prioritised goals.<sup>5</sup> Regrettably, these developing economies have failed to expend sufficiently responsive effort, to efficiently enforce IPRs, this despite the gravity of the negative impact of the proliferation of counterfeits. A statement by Ron Noble the Secretary General of Interpol aptly captures the grave state of affairs thus, "What I find absolutely amazing is that this is a multi-billion dollar problem that affects the safety of people, the security of governments, that is connected to organised crime drug trafficking and terrorism, and no one pressures me to say what I'm doing about this problem. There is no pressure to produce results."<sup>6</sup>

Specifically, according to data from the "World Health Organization (WHO), and the World Customs Organization (WCO); counterfeit medicines are on the rise, and cost the EU pharmaceutical industry €10.2 billion (US \$12.4 billion) a year in lost sales, according to a European Union Intellectual Property Office report with an increased use of e-commerce by the counterfeiters coupled with the difficulty of tracing the source of those selling via these platforms."<sup>7</sup> Counterfeiting is clearly a multi-billion dollar problem compounded unabated, with the growth of e-commerce and the online market place.

Kenya is a comparatively advanced African economy,<sup>8</sup> recently adjudged as having the 3 largest economy in sub-sahara Africa.<sup>9</sup> hitherto having tourism at the core of its economy, but in the recent past, multinationals have been gravitating *en masse* to Kenya, relocating their African headquarters to Kenya.<sup>10</sup> Arguably the attraction is due to an increased diversification of investment opportunities and robust growth prospects anchored in a contentiously enabling

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<sup>5</sup>Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 660.

<sup>6</sup> Lowe P, 'Continuing the fight against fakes' in International Chamber of Commerce, Counter-Intelligence Bureau The International Anti-Counterfeiting Directory, 2005, 5.

<sup>4</sup>Vepachedu R, 'COUNTERFEIT MEDICINES - Code Red now to RACE' published on May, 19 2018 at <https://www.linkedin.com/pulse/counterfeit-medicines-rao-vepachedu-jd-phd-llm/>

<sup>8</sup>Kenya: Grounding Africa's Economic Growth, October 2016 Deloitte, accessed at [https://www2.deloitte.com/content/dam/Deloitte/za/Documents/africa/za\\_Kenya\\_Report\\_Formatted.pdf](https://www2.deloitte.com/content/dam/Deloitte/za/Documents/africa/za_Kenya_Report_Formatted.pdf)

<sup>9</sup>Mboya, E, 'Kenya overtakes Angola as third-largest economy in Sub-Saharan Africa', Business Daily Africa, 5 June 2020,

<https://www.businessdailyafrica.com/economy/Kenya-overtakes-Angola-as-third-largest-economy/3946234-5571578-ag2ukp/index.html>

<sup>10</sup> Mwangi W, 'Big Pharma's healthy contribution', Daily Nation, November 9, 2018, 18.

legal environment.<sup>11</sup> To tap into this economic-promise, Kenya's President resolved to prioritise four key areas, meant to accelerate his administration's development agenda for the country. These are, the provision of affordable housing; Universal healthcare, Food security, Industrialisation, manufacturing and agro-processing.

The Country has also been on an economic-charm-offensive to attract foreign direct investment (FDI) including the Volkswagen<sup>12</sup> and Peugeot manufacturing plants as well as the world's top ten pharma companies all setting up offices directly or through representative offices in Kenya.<sup>13</sup> Further, the local establishment and launch of BBC's largest bureau outside the UK also evinces the increased attractiveness of Kenya as an investment destination.<sup>14</sup> Patently, a robust pharma- industry is thus necessary to realise the country's development aspiration.

Notably thereto, in advancing an enabling local trade environment, Kenya is amongst the first signatories of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS),<sup>15</sup> having contracted the same on 1<sup>st</sup> January, 1995.<sup>16</sup> Significantly, Part III thereof obligates the member states to enforce Intellectual Property Rights, in a manner that facilitates growth of trade.<sup>17</sup> Therefore in pursuing its growth agenda, due regard must be borne to the obligations accruing under TRIPS.

Globally, the International Chamber of Commerce's Counter-Intelligence Bureau (ICC-CIB) published a report,<sup>18</sup> demonstrating counterfeit's dire effects on various manufacturing sub-sectors, vis-à-vis the contemporaneous luxurious outcome for counterfeiters. This nexus between licit businesses' returns and IPR enforcement has obvious consequences on tax collection, unemployment levels,<sup>19</sup> a country's appeal as a business innovation hub and ultimately its ability to develop socio-economically.

IP has increasingly become a key feature of international and regional trade agreements. With globalisation and rise in electronic commerce, there is a contemporaneous rise in counterfeits. Pharmaceutical products are a key target.<sup>20</sup> Kenya cannot successfully pursue its ambitious development agenda and attract FDI, without a responsive enforcement regime against

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<sup>11</sup>Deloitte, *Kenya: Grounding Africa's Economic Growth*, October 2016,

[https://www2.deloitte.com/content/dam/Deloitte/za/Documents/africa/za\\_Kenya\\_Report\\_Formatted.pdf](https://www2.deloitte.com/content/dam/Deloitte/za/Documents/africa/za_Kenya_Report_Formatted.pdf).

<sup>12</sup>Presidential Strategic Communication Unit, 'VW to double locally produced cars, explores second model' Business Daily, Friday 12 January, 2018.

<https://www.businessdailyafrica.com/corporate/companies/VW-to-double-car-production-in-Kenya/4003102-4261866-cl1srp/index.html>.

<sup>13</sup>Mwangi W, "Big Pharma's healthy contribution", 18.

<sup>14</sup>Establishment and launch of BBC's largest bureau outside the UK <https://www.bbc.com/news/world-africa-46096218>

<sup>15</sup>Agreement on Trade Related Aspects of Intellectual Property (TRIPS Agreement) 1<sup>st</sup> January, 1995.

<sup>16</sup>[http://www.wipo.int/wipolex/en/other\\_treaties/parties.jsp?treaty\\_id=231&group\\_id=22](http://www.wipo.int/wipolex/en/other_treaties/parties.jsp?treaty_id=231&group_id=22).

<sup>17</sup>Article 41, TRIPS Agreement.

<sup>18</sup>International Chamber of Commerce Counterfeiting Intelligence Bureau(ICC-CIB), '*Getting a feel of the size of the problem*' International Anti-counterfeiting Directory, 2005, 2.

<sup>19</sup>ICC-CIB, '*Getting a feel of the size of the problem*', 11.

<sup>20</sup>Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 456.

counterfeits. A publication by Nayanah Siva, captures the dangers lurking in a permissive environment, allowing proliferation of counterfeit medication to consumers.<sup>21</sup> He considers the twin outcomes of availing right to health and protecting the IPR holders' rights; and notes that there is urgent need to decisively crack down on counterfeits, not just to safeguard the interests and investments of the pharmaceutical manufacturers but also to protect the lives of many innocent purchasers of the counterfeit medication.

In a study of counterfeiting's demand side, Bloch, Bush and Campbell write about *Consumer accomplices* in product counterfeiting, and note that not all consumers/purchasers of counterfeit products are 'innocent'. They urge that some knowingly purchase that which is counterfeit often due to the *cost* element, but also at times due to *wider distribution* of the counterfeits as opposed to the genuine products. Their study highlights the challenge posed against anti-counterfeiting from the comparative affordability, convenience and accessibility and availability of the counterfeits.<sup>22</sup> Blakeney equally addresses the *consumer accomplice* phenomena by observing that counterfeiting would actually be non-existent without the consumer demand for the counterfeits; and, the misconception of counterfeiting as innocuous infractions.<sup>23</sup> These views establish that effective enforcement will not singularly be targeted at the counterfeiters, but also meaningful enlightenment of consumers against counterfeits.

## 1.2 Problem Statement

The effective enforcement of IPRs is intended to help maximise economic benefits accruing to commercial and industrial activity through fair competition on one part and safeguard consumer welfare of the other. IP, in and of itself, has become an integral part of economic and socio-cultural development globally: especially with the entrenchment of the globally-interlinked national, regional and international IP systems. It is therefore peremptory to adopt innovative, and symbiotic cross-border, approaches to match the challenges faced.<sup>24</sup>

It is undoubtedly true that Kenya's economy has been facing sluggish growth particularly in the country's manufacturing industry – accounting for a meagre 9% of the Country's Gross Domestic Product. Curiously, despite the marginal growth it is also true that Kenya is amongst the fastest growing economies globally, with a macro-economic growth of between 5% and 10%.<sup>25</sup> The current President's ambitious 'Big Four Agenda' evinces the need for measures that will build-on the gains and actualise industrialisation, manufacturing and agro-processing (of the one part) as key focus areas in raising the sector's share from 9% to 15% of Kenya's GDP within five years.<sup>26</sup> This development agenda equally requires funding, which revenue

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<sup>21</sup> Siva N, 'Tackling the booming trade in Counterfeit Drugs' 376 *The Lancet*, 2010, 1725-1726.

<sup>22</sup> Bloch P, Bush R, Campbell L, "Consumer "accomplices" in product counterfeiting: a demand side investigation", 10 (4) *Journal of Consumer Marketing*, 1993, 27-36.  
<https://doi.org/10.1108/07363769310047374>.

<sup>23</sup> Blakeney M, Counterfeiting and Piracy: An Overview', 9.

<sup>24</sup> World Intellectual Property Organisation (WIPO), *Intellectual Property Handbook*, 2<sup>nd</sup> ed, WIPO, 2004, 163.

<sup>25</sup> Common Market for East and Southern Africa (COMESA), 2016-2017 COMESA Biennial Report.

<sup>26</sup> Lang'at P, 'How Uhuru hopes to achieve Big Four agenda' Daily Nation, 24 January, 2018, 4.

(for government) is lost with a contraction of legitimate trade at the expense of illicit trade.<sup>27</sup> Therefore how best to secure the Pharma-industry's growth (being a key sub-set of the manufacturing sector) is an issue of great concern.

The current Jubilee administration projects quality livelihoods, massive job creation and attracting FDI as key outcomes of actualising its campaign manifesto. This it projects to achieve through establishment of manufacturing and processing of leather, manufacturing and processing of cotton, agro-processing and ultimately export leather, and textile products worth KES 7 and KES 20 Billion respectively and creation of jobs within these sectors.<sup>28</sup> The Pharma-industry if properly safeguarded, will facilitate and compliment the actualisation of the projected key outcomes.<sup>29</sup> Investors are less likely to venture into markets where counterfeits are rampant.

These ambitious development initiatives, seeking to position the country as a major economic player, and the obligations accruing from contracting TRIPS, necessitate an examination of the interface between the tri-limb of an effective IP system ranging from creation of IPRs, their lawful exploitation finally through to enforcement. The proper address of this tri-limb, will enable aggressive pursuit of industrial growth, economic development, acquisition and enhancement of technological capability, trade and competition.<sup>30</sup> The Kenyan government, Kenya Association of Manufacturers (KAM) and the Anti-counterfeit Authority (ACA) reckon, that for the economy to grow their must be concerted effort against the counterfeit trade, this as protection of IPRs plays a crucial role in fostering economic development.<sup>31</sup> WIPO observes that, state authorities have to actively play their role, and that civil remedies (singularly/exclusively) are not always sufficient deterrents<sup>32</sup> as the infringers are able to set-up elsewhere. IP owners should be able to call on state authorities to deal with counterfeits.<sup>33</sup>

Further most consumers rely on the label, brand names and packaging when purchasing and pay less attention to the product itself.<sup>34</sup> This is informed by consumer's association of certain brands, with quality and medicinal potency for the genuine product. However, this recognisability, as well goodwill, is regrettably exploited by counterfeiters. Sihanya observes that most pharma-counterfeiters purchase generics and market them through counterfeit packaging, which are widely marketed and sold in many African Pharmacies, supermarkets, shops, bus-stations, catering establishments including through door-to-door sales.

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<sup>27</sup>Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 468.

<sup>28</sup>Kenyan Government Draft 2017/2018 draft policy statement cited in *Daily Nation*, 24 January, 2018, 4, "How Uhuru hopes to achieve Big Four agenda".

<sup>29</sup>Mwangi W, 'Big Pharma's healthy contribution', 18.

<sup>30</sup>Sikoyo G, Nyukuri E, and Wakhungu J, *Intellectual Property Protection in Africa: Status of Laws, Research and Policy Analysis in Ghana, Kenya, Nigeria, South Africa and Uganda*, African Centre for Technology Studies, 2006.

<sup>31</sup>Anti-Counterfeit Agency calls for closer ties to fight vice, *Business Today*, 30 November 2017 <https://businesstoday.co.ke/anti-counterfeits-agency-calls-closer-ties-fight-vice/> on 13 January, 2018.

<sup>32</sup>WIPO, *Intellectual Property Handbook*, 215.

<sup>33</sup>WIPO, *Intellectual Property Handbook*, 207.

<sup>34</sup>Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 458.

According to the WHO, 30% of all medicine marketed and sold in Africa is counterfeit.<sup>35</sup> The ICC-CIB report highlights the magnitude of the problem in various sectors including the pharma-industry where it notes that: “It is estimated that counterfeit pharmaceuticals account for up to 10% of the global market – United States Food and Drug Administration.”<sup>36</sup> Sihanya in discussing the size of the problem observes that 7% of the global pharma products is counterfeit, 60% of which is in African countries.<sup>37</sup> The internet and related ICT technologies are increasingly being used as media for counterfeiting. Through the emerging technologies and increased proliferation of e-commerce, it has become easier for counterfeiters with an enhanced ease of escaping detection where illicit traders operate anonymously, more easily duplicate and avail counterfeit goods but also at times even advertise and offer genuine products for sale but deliver counterfeits.<sup>38</sup>

90% of the pharma-products in Kenya are generics, which are between 70%-90% cheaper than their brandname counterparts.<sup>39</sup> A misconceptualisation between generic and counterfeits, would significantly affect access to affordable healthcare. This confusion is precisely what a broadened scoping of what are counterfeits under Kenyan law, does.

An unabated and thriving illicit pharma-enterprise, caused by an ineffective legal system, negatively impacts the investments and well-being of legitimate pharma businesses; whose genuine products are targeted by counterfeiters. These destroy legitimate markets, reduces their market share and leads to loss of employment with closure of legitimate business.<sup>40</sup> Counterfeit pharma products also negatively affect the health and wellbeing of consumers, as these counterfeit products are often unapproved by the regulatory authorities including the Pharmacy and Poisons Board and the Kenya Bureau of Standards, but also pose a national security risk including through availing funds for criminal enterprise. Some legitimate businesses are constrained to make reparations for product liability issues to consumers, if only to salvage their blurred Trademarks and tarnished reputation incurring further losses.

Kenya has enacted a *sui generis* law targeted at combating counterfeits generally, but as evinced in this study, the anti-counterfeit legal system is ineffective *first* due to its broadened scope as to what under Kenyan Law is counterfeit. The broad scope under Section 2, Anti-Counterfeit Act extends the scope of counterfeit definition not just to any and all registered IP but further to any such IP registered in Kenya and anywhere else in the world. This vague definition creates ambiguities and challenges discussed herein including possible curtailment of right to access healthcare through threatening use of generics as counterfeits.<sup>41</sup> *Secondly* Kenya’s legal system is ineffective for want of capacity in the law enforcement who are now

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<sup>35</sup>Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 463.

<sup>36</sup>ICC-CIB, ‘Getting a Feel for the size of the Problem’, 2.

<sup>37</sup>Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 459.

<sup>38</sup>Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 459, 460 & 461.

<sup>39</sup>Susan Anyanu-Amu, Kenya Anti-counterfeit Law Violates Right to Health; [www.IPSnews.net/2009/12/kenya-anti-counterfeit-law-violates-right-to-health/](http://www.IPSnews.net/2009/12/kenya-anti-counterfeit-law-violates-right-to-health/) on 31 December, 2009.

<sup>40</sup>Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 466 & 467.

<sup>41</sup>Susan Anyanu-Amu, Kenya Anti-counterfeit Law Violates Right to Health.

required to seize IP that they'd otherwise require specialised training to properly discern. Finally, The Kenyan legal system, is unresponsive to the emerging challenge of counterfeits traded through e-commerce, which render some of the remedies currently in law as impractical. Often complications arise on the law to be applied and where to assert the infringement in light of the e-commerce transaction i.e. choice of law and choice of forum questions. Further, the nature of online transactions poses a challenge on effective enforcement as traders (both those involved in counterfeits and genuine goods) are anonymous. The traditional sanctions such as forfeiture, seizure inter alia are also not appropriate.

Nonetheless much as effective counterfeit laws are key, the monopoly inherent in grant of IPRs, also poses a major challenge for a developing economy like Kenya's, where the genuine pharma products are often unaffordable for most. Arguably, the counterfeiters facilitate technology transfer, create employment within their illicit-enterprises; some possibly even remit tax and create competition for legitimate traders – with attendant benefits from competition as that from licit trade.<sup>42</sup>

There is certainly an effectiveness gap, evinced by the tri-issues above, making a clear case for reform of Kenya's anti-counterfeiting law. In so doing is it in the country's greater interest to adopt such stringent enforcement, especially where for pharma products inaccessibility and unavailability invites almost certain literal fatal consequences. Is it available for the IP system to be structured to countenance the interests of traders, manufactures, industrialists, researchers and consumers?

### **1.3 Objectives of the Research**

No meaningful attempts have been actualised to quantify the scale of pharma counterfeiting and the consequences thereof for businesses, consumers and society.<sup>43</sup> This study therefore:

- (i) *First*, establishes the effects of the illicit counterfeit industry on growth of Kenya's pharma-industry<sup>44</sup> vis-à-vis the effect on her socio-economic development.
- (ii) *Secondly*, it explores the efficacy of Kenya's legal regime in the enforcement against counterfeits, as against the core tri-challenges of scoping of counterfeits, the enforcement capacity and the menace of counterfeiting in the online marketplace.
- (iii) *Ultimately*, it demonstrates through recommendations for reform, that aligning Kenya's anti-counterfeiting legal regime, with international best practise; will realise an exponential growth of its pharma industry through better securing the IPRs for innovators and investors in the pharma-industry, erstwhile positively impacting the country's socio-economic development and the access to right to health.

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<sup>42</sup>Sihanya, B, Intellectual Property and Innovation Law in Kenya and Africa.

<sup>43</sup>European Intellectual Property Office (EUIPO), 'Economic Cost of IPR Infringement in the Pharmaceutical Industry (Quantification of Infringement in Pharmaceutical Preparations), 2016.

<sup>44</sup> Mwangi W, 'Big Pharma's healthy contribution', 18

## 1.4 Research Questions

1. What is the effect of counterfeiting on the growth of Kenya's pharmaceutical industry, and the country's overall socio-economic development?
2. What is the current legal system formulated to combat counterfeiting of pharmaceutical products in Kenya, *vis-à-vis* her obligations under various Intellectual Property Treaties; and is Kenya's anti-counterfeiting legal system effective?
3. In mitigating the effects of counterfeiting, what are the recommended solutions from other jurisdictions for enhanced enforcement within the identified tri-core challenges of scoping of what counterfeits are in Kenya, enforcement capacity and counterfeiting in the online sphere?

## 1.5 Literature Review

IPRs have been defined as property in the intangible that protect innovation and rewards innovation activity. Sikoyo, Nyukuri and Wakhungu note that, "IPRs comprise a bundle of rights focusing on the physical manifestations of intellectual activity in any field of human endeavour. IPRs are concerned with the expression of an idea for an invention, the details of which have been worked out and which takes the form of a product or process that can be applied industrially. Development over a century has given rise to various IPRs, which have become well known. These include Patents, Trade and Service Marks, Copyright, rights in performances, Designs, Plant Breeders' Rights, Utility Models, Appellations of Origins, layout designs and topography".<sup>45</sup>

The legal regime established in enforcement of IPRs necessarily impacts the level of innovation and commercialisation of the innovations. However, to determine the efficacy of the regime of protection adopted, a study of Kenya's anti-counterfeit law *vis-à-vis* its international obligations and comparison to the laws adopted in other jurisdictions, is instructive.

Economist Keith Maskus, argues that stronger IPR Protection, translates to increased economic growth and technological development, but only if well-structured.<sup>46</sup> Maskus further cautions, that stronger IPR protection in isolation will not improve prospects of economic growth and development. He argues that there is need to activate an array of other influences including macro and micro economic policies e.g. taxation, support for literary and technological education, openness to international trade and investment of the one part and embedding IP systems within coherent socio-economic policies and transparent regulation of the other. Fisher similarly urges that, "the economic and cultural importance of this collection of IPR rules is increasing rapidly. The fortunes of many businesses and industry now depend heavily on the investment and protection of IPRs." Additionally, the WHO estimates that antimicrobial resistance (AMR) could kill 10 million people yearly by 2050. WHO attributes the growth of

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<sup>45</sup>Sikoyo G, et al, 'Intellectual Property Protection in Africa', 1,

<sup>46</sup>Maskus K, Intellectual Property Challenges for Developing Countries: An Economic Perspective (2001).

AMR to the use of counterfeit drugs that catalyze the resistance against various pharmaceutical regimes as such there are health<sup>47</sup> and security of nations largely threatened by counterfeiters.

Kenyans prefer counterfeit products, due to their general affordability, which allows them access to products and services that would be the preserve of the middle and upper class – this according to a 2011 research by Synovate.<sup>48</sup> The magnitude of the problem especially in Kenya's pharma industry is exposed in A. Jack's 2012 publication *Faking It*. He studied the scale of counterfeiting and attempts to crack down, and observed that reportedly HIV patients in Kenya are affected by Counterfeit ARVs.<sup>49</sup> The ICC-CIB aptly summarise the premise for this study, by asserting that, "effective protection of Intellectual Property is vital to encourage research and innovation, international trade and investment, and sound economic growth and development".<sup>50</sup> It is not enough to provide for creation and recognition of IPRs, and avail opportunities for commercial exploitation, effective IP systems must aptly enforce the IPRs.

It is observed that counterfeits occasion significant negative effects<sup>51</sup> inter alia result in loss of brand value and tarnishing of trademarks, secondly it causes losses in revenue for legitimate business and in turn the revenue they would have paid in taxes. Third the illicit trade leads to a reduction and destruction of market share for the genuine business and even closure of licit businesses ultimately leading to job losses. The consumer is also a big loser as investment in potent pharma products will be dis-incentivised against the backdrop of little to no return on investment innovation.

Susan Sell urges that data, on levels of counterfeiting is inauthentic and deliberately conjured up by fear-mongering business interests to urge for stronger IPR protection. Worse still she observes the linkages of counterfeits to security threats and health, and maximalising the scope of IPRs that are amenable to criminal enforcement, is a global scheme to protect private interest using public resources.<sup>52</sup>

It has similarly been urged that a weakened or less strenuous enforcement against counterfeits is good for initial growth. In making a case for the weakened enforcement systems in developing economies, it has been urged that supposedly such absence enforcement will help these governments save on forex exchange, that would otherwise have been spent on genuinely importing the technology. The saved forex would be applied to other pressing needs. Further the proponents of this supposition urge that this will enable the pharma-industry grow expeditiously and often the Swiss, Indian and Pakistani pharma-industries are cited as examples. Counterfeit trade supposedly further facilitates technology-transfer, increases

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<sup>47</sup>Vepachedu R, 'COUNTERFEIT MEDICINES - Code Red now to RACE'

<sup>48</sup>Business Daily Online, "Survey shows why Kenyans opt for goods from China" published on 2 March, 2011 [http://www.businessdailyafrica.com/Corporate+News/Survey+shows+why+Kenyans+opt+for+goods+from+Chi na/-539550/1117194/-/view/printVersion/-/1q9jei/-/index.html](http://www.businessdailyafrica.com/Corporate+News/Survey+shows+why+Kenyans+opt+for+goods+from+China/-539550/1117194/-/view/printVersion/-/1q9jei/-/index.html)

<sup>49</sup>Jack A, 'Faking It' 345 7884, *The British Medical Journal*, 2012, 28-29.

<sup>50</sup>ICC-CIB, 'Getting a feel of the size of the problem' *The International Anti-Counterfeiting Directory* (2005), 3,

<sup>51</sup>Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 466 & 467.

<sup>52</sup>Sell S, *The Global IP Upward Ratchet, Anti-counterfeiting and Piracy Enforcement Efforts: The State of Play*, 2010, PIJIP Research Paper No 15 American University Washington College of Law, Washington DC.

choices for consumers and creates competition for legitimate traders.<sup>53</sup> These short to mid-term benefits are however far outweighed by the need to effectively curb the counterfeits due to the entrenched negative impact.

Is the enforcement regime complicit on existence of ‘illicit-innovation’ through a thriving ‘black-market’ of counterfeits? ‘Illicit-innovation’ must be addressed holistically including a review of how competition can be lawfully facilitated, without compromising or diluting the protection of IPRs. India offers an excellent exposition with the accessibility to affordable healthcare.<sup>54</sup> The commercial implication of an effective intellectual property protection is a significant policy consideration,<sup>55</sup> which would position Kenya as an ideal investment destination that facilitates industry. IPRs are characteristically inherently territorial, as well as the national treatment principle under Article 3, TRIPS: but the world is increasingly becoming one global e-market; with increased reliance on imports/exports and the interventions identified must necessarily address this challenge. Investors are less likely to venture into markets where counterfeits are rampant, which is what an ineffective legal system enables.

Africa is increasingly becoming a globally recognized destination as well as a transit for counterfeit goods destined for European and American markets, according to the World Customs Organisation’s Counterfeiting and Piracy Unit.<sup>56</sup> Attempts continue to be made to redress this through various international agreements to enhance effective enforcement of IPRs. “...Intellectual property has increasingly become a strong feature of international, regional trade arrangements and national legal instruments. From multilateral to regional and bilateral trade relations, IP issues almost inevitably come to the fore as a critical issue to be considered in any deals that are struck. An example of these regimes is the free trade agreements that have become a feature in international trade relations. The United States has concluded such agreements with Latin and Central American and Caribbean countries individually, in groups and collectively. It also has an agreement with Australia, Morocco, the South African Customs Union (SACU) countries, Singapore and Thailand”.<sup>57</sup>

The environment within which counterfeits thrive has been identified under TRIPS where members recognise that they must “reduce distortions and impediments to international trade, taking into account the need to promote effective and adequate protection of IPRs, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become

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<sup>53</sup>Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 472.

<sup>54</sup> Deepak S, ‘Patents and Competition Law: Identifying Jurisdictional Metes and Bounds in the Indian Context’ 27(2) *National Law School of India Review*, 2015, 135-146.

<sup>55</sup> Duffy J, and Hynes R, ‘Statutory Domain and the Commercial Law of Intellectual Property’ 102(1) *Virginia Law Review*, 2016, 1-77.

<sup>56</sup>Haman M, ‘Africa rising to the anti-counterfeiting challenge’ 5(5) *Journal of Intellectual Property Law & Practice*, 2010, 344–349.

<sup>57</sup>Musungu S, ‘General Trends in the Field of Intellectual Property: Issues and Challenges for the Establishment of a Development Oriented Framework,’ Regional Dialogue on Intellectual Property Right, Innovation and Sustainable Development in Eastern and Southern Africa, Organized by the International Centre for Trade & Sustainable Development (ICTSD), the United Nations Conference on Trade and Sustainable Development (UNCTAD) and Trade and Industrial Policy Strategies (TIPS), 29 June-1 July, 2004, Cape Town, South Africa,

barriers to legitimate trade.”<sup>58</sup> As with barriers to legitimate trade, illegitimate trade will find a niche and a need to exploit. Jeremy M. Wilson et al, urge for anti-counterfeiting legislation that enable legitimate trade but effectively proscribe and punish counterfeiters.<sup>59</sup> Sell, acknowledges that what constitutes counterfeit varies from jurisdiction to jurisdiction.<sup>60</sup> Kenya having elected to adopt a much broad conceptualisation of counterfeits, a super TRIPS compliant conceptualisation with no apparent benefit to enforcement against counterfeits.

To understand the challenge posed in actualising this, regard must be had to the limitations posed by counterfeiting.<sup>61</sup> Bush R et al, observe,<sup>62</sup> that counterfeiting has continued to negatively impact businesses across the world; and in detailing the negative effects of counterfeiting further urge that unchecked counterfeiting could affect the world’s economy.

There is certainly a need to effectively curb the prevalence of counterfeits. Globalisation has increased the risk related to counterfeit drugs, however Jack A’s article observes that pharma-companies are reluctant to share the data and statistics on the high proliferation of counterfeit drugs due to fears of undermining public confidence in their products.<sup>63</sup> Sikoyo G, Nyukuri E, and Wakhungu J<sup>64</sup> in reviewing the status of laws, research and policy in select African Countries including Kenya, Nigeria, Ghana, South Africa and Uganda, urge for reform. However, they caution that important lessons from comprehensive measures adopted in the West,<sup>65</sup> cannot be limited to routine enactment of legislation and establishment of state agencies to address the menace of counterfeit. Due regard must be placed on the international community and private sector players as well as discerning the obligations accruing therefrom. Connected thereto Sihanya highlights that most Anglo-phone African countries like Kenya hitherto ‘imported’ the UK Trademarks Act, 1938 which did not have provisions designed to respond to wilful Trademark infringement as a criminal offence (the UK only amended their law in 1988 to make provision for this).<sup>66</sup> With the enactment of TRIPS and the obligations under Article 61, which enjoins member states to provide for criminal prosecution and penalties for wilful trademark and copyright infringement at a commercial scale,<sup>67</sup> some African countries like Kenya and South Africa have *sui generis* laws to combat counterfeit.

Allan Sykes importantly highlights the dangers developing countries are exposed to due to poor enforcement of IPRs for pharma companies and he reckons that it has de-incentivized research

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<sup>58</sup> Preamble, TRIPS Agreement.

<sup>59</sup> Wilson J, Sullivan B, Johnson T, Fenoff R and Kammel K, ‘Product Counterfeiting Legislation in the United States: A Review Assessment of Characteristics, Remedies and Penalties’ Journal of Criminal Law and Criminology, 2016, Vol 106.

<sup>60</sup> Sell S, *The Global IP Upward Ratchet, Anti-counterfeiting and Piracy Enforcement Efforts*, 7.

<sup>61</sup> ICC-CIB, ‘Getting a Feel for the size of the Problem’, 2.

<sup>62</sup> Bush R, Bloch R, Dawson S, “Remedies for product counterfeiting” 32(1) *Business Horizons*, 1989, 59 - 65.

<sup>63</sup> Jack A, ‘Faking It’, 28-29.

<sup>64</sup> Sikoyo G, et al, ‘Intellectual Property Protection in Africa’.

<sup>65</sup> Sodipo B, ‘Piracy and Counterfeiting: GATT, TRIPS and Developing Countries’ (1997) *Kluwer Law International*.

<sup>66</sup> Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*.

<sup>67</sup> ICISP-UNCTAD Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement, 2004.

into ‘tropical’ diseases that have afflicted developing nations for a long time.<sup>68</sup> Sihanya also enumerates the numerous negative effects of prevalent counterfeits, in demonstrating that the short to medium term benefits that may accrue from a permissive environment is long term detrimental to developing countries.<sup>69</sup>

Significantly, Jack’s (2012) publication notes that there is an apparent averseness in publishing detailed data on the scale of pharma-counterfeits due to possible merchant-fears of eroding confidence in particular pharmaceutical products. He further notes that even the World Health Organisation (WHO) curiously does not keep an updated data base on the apparent huge magnitude of counterfeit pharma-products.<sup>70</sup> Sikoyo G, et al similarly note that there is limited literature on the effect of IPRs violations on trade and economic development; which suppositions necessitate inquiry by way of this study.<sup>71</sup>

Additionally, Bush R, et al on their part urge for a critique of the role of the consumer in the proliferation of product counterfeiting,<sup>72</sup> through what they describe as ‘*consumer accomplices*’. They argue that a significant adult population knowingly acquire counterfeit products – regardless of the risks attendant - where there is a price advantage: confirming that a review and remedy to the problem cannot be to the exclusion of the role of the consumer. Indicating that costs and accessibility of the genuine pharma-products impact the prevalence of counterfeits.

It is therefore impossible to defer effective counterfeiting, but even more critically to facilitate growth of the pharmaceutical industry and the attendant socio-economic benefits: there is a need for an effective legal system geared at combating counterfeiting. The effective legal system striking a balance between consumer protection, investor/IPR owner and government.

## 1.6 Research Hypothesis

This study hypothesizes that, Kenya has an ineffective anti-counterfeiting legal regime, which regime is negatively influencing the growth of her pharmaceutical industry.

This study further hypothesizes that the adoption of efficacious preventive and enforcement anti-counterfeiting measures, will positively influence the exploitation of the country’s pharmaceutical industry and Kenya’s overall socio-economic development.

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<sup>68</sup> Sykes A, TRIPS, Pharmaceuticals, Developing Countries and the Doha ‘Solution’, 2002.

<sup>69</sup> Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 468

<sup>70</sup> Jack A, ‘Faking It’, 28-29.

<sup>71</sup> Sikoyo G, et al ‘Intellectual Property Protection in Africa’, (2006).

<sup>72</sup> Bloch P, Bush R, Campbell L, "Consumer “accomplices” in product counterfeiting: a demand side investigation", 27-36.

## 1.7 Theoretical Framework

This research proceeds on the premise of the *utilitarian theory*, propounded by Jeremy Bentham; which, in the context of this study, observes that the enforcement and protection of IPRs by curbing proliferation of counterfeits necessarily results in the greatest benefit for the greatest number of the Kenyan citizenry. Effective fighting of counterfeit pharma-products will incentivize innovation, and greater quality amongst manufacturers who will be assured of returns. Effective enforcement will similarly eliminate the often dangerous counterfeit-pharma from circulation, protecting the citizenry from the harmful effects.

Allan Sykes further highlights this premise by urging that failure to offer effective IPR protection to pharma companies has de-incentivised research into diseases that plague developing countries.<sup>73</sup> Development of successful pharma-products requires great skill and judgment: before a product goes to market it requires expensively tedious regulatory approvals, clinical trials, huge marketing costs and additionally acquiring and safeguarding the IPRs through Trademarks and Patents.<sup>74</sup> Assurance of recovery of these expenses critical incentive for the pharma-companies.

This research in investigating the efficacy of apt anti-counterfeiting measures on Kenya's pharma-industry, is anchored against this theoretical framework, and as further urged by Fisher's three-fold exposition of "*Utilitarianistic: IP conceptualisation*". He notes that three sub-sets/approaches of this utilitarianistic legal school of thought abound *viz*:

### 1.7.1 Incentive Theory

Fisher discusses this approach by illustrating William Nordhaus's exposition on Patent law; which Fisher urges can be applied generally on protection of Intellectual Property; thus, "...Each increase in the duration or strength of patents, he observed, stimulates an increase in inventive activity. The resultant gains to social welfare include the discounted present value of the consumer surplus and producer surplus associated with the distribution of the intellectual products whose creation is thereby induced."<sup>75</sup> Proliferation of counterfeits will negate this object, as this research demonstrates. The converse is equally true, that R&D will be encouraged, through a guaranteed fair opportunity of return on investment.

This paper's premise is supported by Sihanya's supposition that effective enforcement (through redressing the tri-issues herein) translates to good returns for IPR holders, creation of jobs in the sector to help exploit the IPRs and realise revenue for government.<sup>76</sup>

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<sup>73</sup>Sykes A, TRIPS, pharmaceuticals, developing countries and the Doha 'solution', 2002.

<sup>74</sup>Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 445.

<sup>75</sup> Nordhaus WD, Invention, growth, and welfare: A theoretical treatment of technological change, 1969, Cambridge: M.I.T. Press. cited at page 8 in William Fisher's Essay Theories of Intellectual Property, <http://www.law.harvard.edu/faculty/ffisher/iptheory.html>.

<sup>76</sup> Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 456.

### ***1.7.2 Optimizing Patterns of Productivity Theory***

Proponents of this approach urge that, “the copyright and patent systems play the important roles of letting potential producers of intellectual products know what consumers want and thus channelling productive efforts in directions most likely to enhance consumer welfare”.<sup>77</sup>

Paul Goldstein as cited by Fisher notes that, “...The logic of property rights dictates their extension into every corner in which people derive enjoyment and value from literary and artistic works. To stop short of these ends would deprive producers of the signals of consumer preference that trigger and direct their investments.”<sup>78</sup> Drawing a nexus between the investments put in by IPR owners and the level of protection accorded to their inventions and innovations.

Protection of trademarks is the law’s recognition of the psychological function of symbols. If it is true love symbols, it is no less true that we purchase goods by them.<sup>79</sup> This heavily underscores theoretical premise for this paper, in highlighting the need to protect the consumer and assuring her of the source of a particular product associated with a certain Trademark but also protect the owner of the Trademark from persons riding on the notoriety of her brand/symbol.

### ***1.7.3 The Rivalrous Invention Theory***

The third approach urged by Fisher is one which concerns what he describes as, an “objective to eliminate or reduce the tendency of intellectual-property rights to foster duplicative or uncoordinated inventive activity.”<sup>80</sup> This approach focuses on the effect of competition among firms to develop and patent rights, necessarily addressing economic waste that is likely to arise from an imprudent application of IPRs – not within the province of the research herein.

William Fisher, further captures the relevance of utilitarianism in development of an understanding of Intellectual property by urging that, “The primary economic benefits of trademarks, they contend, are (1) the reduction of consumers' "search costs" (because it's easier to pick a box of "Cheerios" off the grocery shelf than to read the list of ingredients on each container, and because consumers can rely upon their prior experiences with various brands of cereal when deciding which box to buy in the future) and (2) the creation of an incentive for businesses to produce consistently high-quality goods and services (because they know that their competitors cannot, by imitating their distinctive marks, take a free ride on the consumer good will that results from consistent quality). Trademarks, Landes and Posner claim, also have an unusual ancillary social benefit: they improve the quality of our language. By

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<sup>77</sup> Demsetz H, "Information and Efficiency: Another Viewpoint," 12 *Journal of Law and Economics*, 1969, 1.

<sup>78</sup> Goldstein P, "Copyright's Highway," *Hill & Wang*, (1994), 178-179 cited at Page 8 in Fisher W's Essay, *Theories of Intellectual Property* <http://www.law.harvard.edu/faculty/ffisher/iptheory.html>.

<sup>79</sup> Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 458.

<sup>80</sup> Fisher W, *Essay, Theories of Intellectual Property* <http://www.law.harvard.edu/faculty/ffisher/iptheory.html>.

increasing our stock of nouns and by “creating words or phrases that people value for their intrinsic pleasingness (*sic*) as well as their information value,” they simultaneously economize on communication costs and make conversation more pleasurable.”<sup>81</sup>

In this instance this study interrogated the observation by Sikoyo G, et al,<sup>82</sup> that Intellectual Property Rights are intricately related to trade, competition, industrial growth and economic development. They observe that IPRs incentivise innovation and invention as mechanisms for market protection.

Fisher aptly sums up this concern and observes that, “empirical work has suggested that patent law has been more important in stimulating innovation in certain industries (e.g. pharmaceuticals and chemicals) than in others, but has failed to answer the ultimate question of whether the stimulus to innovation is worth its costs.”

## 1.8 Research Methodology and Approach

This study is structured within the framework of a descriptive design in ascertaining the extent and effect of proliferation of counterfeit products within Kenya’s pharmaceutical sub-sector. The study aims at discerning the efficacy of legal regime established to curb the counterfeits.

This study relies on an examination of primary data and subsequently analyses of trends from the pharma-industry, on the levels of counterfeits in Kenya’s pharma-industry. Separately, the study extensively reviews secondary data obtained from literature in books, journal articles, research reports *inter alia* on various issues such as foundational questions on utility of Intellectual Protection (and particularly anti-counterfeiting as a key component of IP protection systems) in developing economies *vis-à-vis* the effect on socio-economic development; against the background of increased globalisation in trade.

In data collection, aside from reviewing reports prepared from with Kenya’s key enforcement agencies on matters of pharma-counterfeiting i.e. the Anti-counterfeit Authority<sup>83</sup> (ACA), the Kenya Bureau of Standards<sup>84</sup> (KEBS), the Kenya Revenue Authority<sup>85</sup> (KRA), the Pharmacy and Poisons Board (PPB) and the Kenya National Bureau of Statistics (KNBS) this research also interrogates reports by key players within the pharma-industry.

The research identifies select case studies from which it can pursue in-depth reviews of the research questions posed herein. This paper addresses some self-help anti-counterfeiting measures; the effect of this strategy and the variations on the effect on their businesses if any.

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<sup>81</sup> Fisher W, Theories of Intellectual Property.

<sup>82</sup> Sikoyo G, et al, ‘Intellectual Property Protection in Africa.

<sup>83</sup> Section 3, Anti-Counterfeit Act No 13 of 2008 Laws of Kenya.

<sup>84</sup> Section 4, Standards Act Chapter 496 Laws of Kenya.

<sup>85</sup> Section 2, Kenya Revenue Authority Act No 2 of 1995 Laws of Kenya.

Ultimately recognising the territorial nature of IPRs, the research additionally approaches the enquiry hereon through a comparative study of the measures adopted and employed by the United States of America to curb counterfeits and the effect on the pharma sub-sector. Additionally, the research considers the approaches by the Republic of South Africa in anti-counterfeiting measures as a strong influence for the growth of their pharmaceutical industry.

### **1.9 Limitations and Assumptions**

The study is limited to a review of the pharmaceutical sector due to a presumption that this sub-sector within the larger manufacturing sector is the most targeted for counterfeiting. Further, the research in adopting a non-probabilistic sampling method, will be confined to a review of purposefully identified corporates within the pharmaceutical manufacturing sub-sector. This sampling may expose the research to peculiarities of the sampled corporates.

This research also recognises other influences at a macro and micro level on the growth of a sustainable pharmaceutical manufacturing industry in Kenya, including responsive government policies on taxation, cost and availability of various factors of production. Ultimately, redressing counterfeiting may not of itself solely revamp Kenya's pharma-manufacturing industry and positively influence the growth of this industry. The particular role and proportional impact of these inter-related influences have not been considered in this study.

Various Kenyan law establishes numerous classes of Intellectual Property Rights, however this paper considered what it determines as key Intellectual Property Rights, as defined by the Kenyan Anti-counterfeit law, that are the subject of counterfeiters targeting the pharma-manufacturing sector i.e. Trademarks.<sup>86</sup> In discussing the efficacy of the Kenyan legal regime in enforcement against counterfeits, the paper does not extend to the question of observance of rule of law in Kenya, a subsequent concern after establishment of a responsive legal regime.

As admitted in various studies cited herein, most corporates are not willing to divulge actual data/statistics on the extent of counterfeits against their IPRs. This reluctance is due to (mis)apprehension of possible negative perception(s) from consumers of their products who might refrain from further purchases due to feared inability to distinguish counterfeits from authentic. Ms Rita Hayes, the Deputy Director General, WIPO charges that "The private sector has to let us know exactly what we're looking for. How do you get governments to pay attention if you don't have good statistics?"<sup>87</sup> This limitation on availability of reliable statistics necessarily impacted the outcomes of this study, but its is mitigated by data compiled from various empirical studies and reports considered in this paper.

The research was limited by unavailability of updated reports; especially from government agencies relevant to this study on the IPR enforcement regime. To redress this challenge, the

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<sup>86</sup>Vepachedu R, 'COUNTERFEIT MEDICINES - Code Red now to RACE'.

<sup>87</sup> ICC-CIB, 'Getting a feel of the size of the problem', 3.

research reached out directly to the leadership of these state agencies. There was also a limitation of time within which to conduct indepth fieldwork and/or interviews, which interviews would have helped to fact-check the reports.

The research faced a limitation in unavailability or limited availability of verifiable data on the quantity of counterfeit pharmaceutical drugs in Kenya, which was intended to be necessary in drawing various empirical inferences in this paper. The paper relied on secondary reports.

### **1.10 Chapter Breakdown**

This study is structured into four chapters with the first chapter availing a context for issues which the paper sets-out to address. It introduces Kenya's pharmaceutical sub-sector's current sub-optimal performance. It further supposes that pharma-sector's growth is hampered by the proliferation of counterfeits. It explores introduces various literature and explores the utilitarianism theory as a rationale for recognition and enforcement of IPRS.

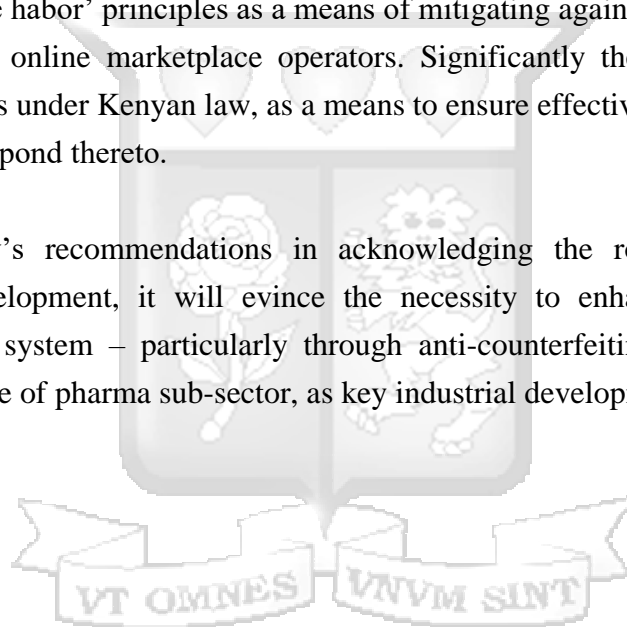
The second chapter reviews the legal regime currently obtaining in Kenya on counterfeiting. It considers international treaties and municipal law enacted to curb pharma-counterfeiting. These laws establish various institutions including the Anti-Counterfeit Authority (ACA), the Kenya Revenue Authority (KRA), the Kenya Bureau of Standards (KEBS), the Pharmacy and Poisons Board whose mandates are intended to curb pharma-counterfeits. It considers the extent of the civil legal regime contiguous to curbing pharma-counterfeits. The second chapter also considers the scope of protection availed through the very definition of counterfeit(s) under the Kenyan anti-counterfeit legal regime *vis-à-vis* the standards of the country's obligations under various IP treaties; being minded of the territoriality of IPRs. The chapter interrogates the definition and conceptualisation of the scope of what is counterfeit under Kenyan law; as well as the governance and institutional challenges in enforcement of counterfeits. This chapter concludes by ultimately considering Kenya's policy considerations Kenya in enforcement against pharma-counterfeiting and how the judiciary has applied these laws to give effect to IPRs threatened with counterfeited.

The third chapter examines the causal effect (*if at all*) of counterfeiting on growth of the pharma-sector. It considers the data and statistics on the extent of counterfeits afflicting the Kenyan pharma-sector. In further setting out an exposition of the extent of counterfeits within this sector, the chapter considers the three (3) core challenges identified as impeding the country's current enforcement regime in curbing counterfeit with particular focus on *first*, scoping of counterfeits; *secondly* inadequate capacity of the enforcement agencies; and *lastly*, proliferation of counterfeit pharma in the online market place. Subsequent to highlighting these challenges, the chapter equally focuses on a comparative study of the best practices on the curbing the counterfeiting menace, in the Republic of South Africa and the United States of America.

Chapter Four will itemise the findings of this study and it will address the efficacy of the solutions that are available to curb counterfeits and recommendations to effectively enforce IPRs to boost the pharma industry in Kenya and lessons learnt especially against the identified core challenges.

The research will conclude by recommending reform measures to the Kenyan legal regime with regard to its stratification and scope of counterfeits, enforcement measures available. At a regional level this paper will urge for reciprocity in the IPR laws of EAC member states and subsequent recognition of registrations in member states allowing for cross-border seizure raids. Indeed, this research also explores the effective use of public campaigns, market survey and pricing by the foreign pharmaceutical companies in a manner responsive to Kenya and possibly urge for active pursuit of generics to avoid genuine pharma-drugs pricing themselves into the hands of counterfeiters. The paper explores available self-help measures to curb counterfeits in the online market place, as well as consideration of possible extrapolation of the exceptions to the ‘safe harbor’ principles as a means of mitigating against facilitation of online infringement through online marketplace operators. Significantly the paper addresses the scoping of counterfeits under Kenyan law, as a means to ensure effective enforcement and the ACA’s capacity to respond thereto.

Ultimately the study’s recommendations in acknowledging the role of an IP system wholesomely in development, it will evince the necessity to enhance the enforcement component of an IP system – particularly through anti-counterfeiting - as a measure of invigorating the uptake of pharma sub-sector, as key industrial development.



## 2.0 Chapter Two: Analysis of Kenya's Legal System postulated to Curb Pharma-Counterfeiting

Globally, the Pharmaceutical sector is understandably a highly regulated sector due to its direct impact on human health, and its potential for huge returns for innovators and investors. As a preliminary this paper notes that a responsive legal system would need to address a balancing of these often-competing interests. Consequently, the legal system targeted at curbing counterfeiting of pharmaceutical products is, in most jurisdictions, the subject of a myriad laws and regulations. This regime includes laws applicable to the registration of pharmaceutical products before sale; protection and enforcement of intellectual property rights; criminal and penal proscription; to customs and border control; consumer protection *inter alia*

Kenya is certainly no exception, and has enacted various national legislation to regulate her pharma-sector. This legal regime includes civil law remedies as well as penal provisions specifically intended to alleviate counterfeiting, including pharma-counterfeits. Significantly, Kenya is a signatory of the World Trade Organisation's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) which enjoins her to observe defined minimum levels in border measures and criminal IPR protection, erstwhile alleviating barriers to legitimate pharma trade.<sup>88</sup> Ergo, this chapter considers Kenya's legal regime and more particularly its efficacy in eradicating pharma counterfeiting as against this international standard. However, much as this paper centres its discussion on the Kenyan legal regime and its efficacy, it acknowledges the concomitant challenge on disregard and/or non-observance of the rule of law in Kenya, apt legal provisions notwithstanding evinced through repeated disregard of court orders by the government and members of the public.

Kenya's Constitution promulgated on 27<sup>th</sup> August, 2010 and billed as one of the most progressive constitutions globally, particularly on its entrenchment of fundamental rights and freedoms, it variously recognises and entrenches the protection of IPRs.

First, the Constitution under Article 2(6) provides that "any treaty or convention ratified by Kenya shall form part of the law of Kenya under this Constitution"<sup>89</sup>. Nonetheless, Kenya has enacted the Treaty Making and Ratification Act, No. 45 of 2012, intended to give effect to Article 2(6) of the Constitution, by providing the manner of executing and subsequently domesticating international treaties to which Kenya becomes a signatory. The significance of this constitutional provision is *inter alia* the legal recognition of Kenya's obligations accruing under various IPR related treaties particularly the TRIPS to *wit* she is a signatory.<sup>90</sup> Ergo in establishing an apt regime, regard must be had to the obligations accruing under the various treaties.

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<sup>88</sup> Article 41, TRIPS Agreement.

<sup>89</sup> Article 2(6), Constitution of Kenya, 2010

<sup>90</sup> Allan Tuli, 'The constitutional framework for the protection of I.P rights in Kenya', 8.

Secondly, Article 11(2)(c), Constitution of Kenya enjoins the state to protect the IPRs of the people of Kenya. The State is equally enjoined with the responsibility to protect property as well as enhance intellectual property rights of the people of Kenya under Article 40(5) as read with Article 260, which later provision defines property to include intellectual property. So that the obligation to curb counterfeiting is imposed as against the state as a public law right.

Concomitantly, Article 46, Constitution of Kenya provides, in the context of this study, for the right to pharma-products of reasonable quality that protects the health, safety and economic interests as well as the right to compensation for losses arising from defects in pharma-products. Whereas, Article 43 further provides for every person's right to the highest attainable standard of health, which includes the right to health services. Against these additional entrenchments the Kenyan Constitution does proscribe counterfeit pharma which might have the effect of negating these entrenchments.

Under Article 2(1), the Constitution binds all state organs at all levels of government, and the obligations afore-referenced enjoin the Kenyan government to at all levels recognize, protect and enforce pharma-IPRs including observance of internationally covenanted minimum standards. The enforcement of IPRs, which characteristically includes curbing counterfeiting vis-à-vis Kenya's pharma-sector therefore has demonstrable strong constitutional underpinning. This Constitutional entrenchment is significant in asserting the protection of the rights accruing to holders of pharma-IPRs.

## **2.1 Civil law regime against counterfeiting**

Kenya has a litany of civil laws enacted to recognise and protect against IPR infringement through availing civil remedies i.e. private law rights. These include the Kenya Copyright Act, 2001 (as amended), the Industrial Property Institute Act, 2001, The Trademarks Act, CAP 506, and the Seeds and Plant Varieties Act. These laws protect various 'genres' of intellectual property rights (IPRs). These ordinarily require the IPR owner undertaking enforcement action in the nature of a suit contending alleged infringement of their property rights.

Connected thereto Kenya has equally enacted various statutory enactments with the effect of fighting counterfeits but still largely falling as civil law remedies. These include the Standards Act, CAP 496, Weights and Measures Act, CAP 513, Law of Contract Act, CAP 23, Competition Act, 2010, Kenya Revenue Authority Act, 1995 (import and export regulation), Sale of Goods Act, CAP 31, Registration of Business Names, CAP 499 as well as common law. These legislations essentially concern contractual liability and product liability; tortious liability and breach of statutory duty. More significantly these pieces of legislation focus of conventional (physical) goods and as Sihanya notes, 'are often fossilized versions of similar statutes from the United Kingdom, United states of America or even common law.'<sup>91</sup> These are highly unresponsive and certainly ineffective pieces of legislation for purposes of curbing

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<sup>91</sup> Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 487.

pharma-counterfeits or even counterfeits generally. It is for these reason that with signing of the TRIPS in 1995, and the obligations accruing for effective provision of a legal system for prevention and obtaining of remedies for infringement of conferred rights – it became necessary for Kenya to consider enactment of an appropriate regime making provisions for border control measures and criminal sanctions in compliance with Article 61, TRIPS.

Materially this research urges for accurate scoping of counterfeits through conceptualisation this as limited to wilful trademark counterfeiting: and those trademarks registered in Kenya. As such it is significant to particularly consider the law under which trademarks are registered in Kenya.

Trademarks in Kenya may be registered under Section 12 and 13 of the Trademark Act for distinctive marks or those adopted to distinguish. Section 7 and 8 itemise the rights conferred upon registration. A trademark owner may institute proceedings at the High Court contending that her trademark has been infringed contrary to Section 7 and/or 8, Trademarks Act. The Relief ordinarily issued upon success in court involves an injunctive order, an order for damages, account for profits and an order for delivery up for destruction essentially private rights; enforced by IPR owners themselves.

However, in as far as counterfeiting and criminal offences involving trademarks are concerned the Trademarks Act only concerns itself with offences of falsification of entries in the trademark register, and falsely representing that a mark is a registered trademark whereas it is not under Sections 57 and 58, Trademarks Act respectively. Further Sections 57C and 57D prohibit forgery of a registered trademark and ultimately Section 58E proscribes sale or importation of goods with a forged registered trademark. The maximum penalty here is a fine of KES 500000 (Approx. USD 5000) and/or 5 years imprisonment.

Rutenberg et al however urge that the Kenya Industrial Property Institute (KIPI) which administers trademarks in Kenya, plays a limited role –if at all- in enforcement of trademarks; but that in any event this role centers on adjudging opposition and rectification proceedings under Sections 21 and 35 Trademarks Act. They additionally urge that infact KIPI's none involvement in enforcement is part of reason that led to creation of the Anti-counterfeit Authority (ACA).<sup>92</sup>

## **2.2 Criminal law regime against counterfeiting**

Kenya's primary applies the Anti-Counterfeit Act, 2008, (as amended) as complemented by the Pharmacy and Poisons Act, CAP 244, as well as the Penal Code, CAP 63; and the Kenya Revenue Authority Act, 1995.

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<sup>92</sup>Rutenberg, I, Ouma M and Munyi P, 'Kenya': In International Encyclopedia of Laws: Intellectual Property Law (ed) Hendrik Vanhaes Alphen aan den Rijn: Kluwer Law International, 2019, 159.

### 2.2.1 The Anti-Counterfeiting Act, 2008 (as amended)

The Anti-Counterfeit Act is the primary legislation enacted to prohibit trade in counterfeit goods in Kenya. This law<sup>93</sup> creates various offences, defines the scope of protection but also establishes enforcement organs including the Anti-Counterfeit Authority (ACA) and the ACA's functions being defined thereunder as well.<sup>94</sup> Before the enactment of this law, in 2008, the Penal Code CAP 63 acted as the main legislation against counterfeiting (through provisions enacted in 1957 and amended in 1962!).<sup>95</sup>

Of Particular importance to this study is the *scope* the Act accords to *counterfeits*, and consequently the *scope* of what the law proscribes as counterfeits, and confers anti-counterfeit protection to. This has been highlighted in this study as one of the 3 core challenges hampering the effective enforcement against counterfeit pharma.

In addition to enlightening and informing the public, combating counterfeiting trade and other dealings in Kenya, the ACA is required to co-ordinate with national, regional and international organizations in counterfeiting. The amended Act includes an advisory role for the ACA in respect of the Cabinet Secretary on how best to promote and protect IPRs, as well *the extent of counterfeiting*. It is equally enjoined to conduct studies on counterfeiting and protection of IPRs<sup>96</sup>. The recent amendments appear to evince a systematic increase in the ACA's mandate and scope of protection accorded to IPR holders.

The Act problematically defines counterfeit, *first* as the unauthorised use (within a commercial context) of intellectual property registered in Kenya, or elsewhere (*outside Kenya*). This blurs the well-recognised principle on territoriality within intellectual property law. On an enforcement perspective, this provision confers protection to IPRs registered outside Kenya and outside the recognised registration systems that would ensure standards set in other legislations have been met. *Secondly*, The Act also defines with specificity what counterfeiting in the context of medicine would be said to extend to.<sup>97</sup> However, wholesomely other IPRs obtaining in pharma products including pharma-patents would otherwise avail themselves to the protection available under the Act, but seemingly in conflict with the very same Act in its definition of counterfeit medicine. The attempt at having a *sui generis system*, on the contextualisation appears to be creating a contradiction and challenge in implementation. *Third*, (*ancillary to the scope of protection created under the definition of counterfeit under the Act*) a new provision of the Anti-Counterfeit Act at Section 34B is the establishment of a Trademarks Recordation system that empowers the ACA to create a mechanism for registration of trademarks. The system is detailed setting out the criteria and procedure for registration including allowing for removals. This system is intended to aid the ACA better monitor

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<sup>93</sup> Section 3, Anti-Counterfeit Act, 2008, (as amended by the Statute Law (Miscellaneous Amendments), No 18 of 2018).

<sup>94</sup> Section 5, Anti-Counterfeiting Act, 2008.

<sup>95</sup> Sections 380 – 381, Penal Code, CAP 63 Laws of Kenya.

<sup>96</sup> Section 5(da) and (db), Statute Law (Miscellaneous Amendments), No 18 of 2018.

<sup>97</sup> Section 3, Anti-Counterfeit Act, 2008.

imported counterfeit products into the country at various points of entry. The ACA is yet to publish the regulations (*including affixing the attendant fees for the recordation*) operationalizing this provision, which is scheduled for enforcement effective 1<sup>st</sup> July, 2019.

The TRIPS has created minimum obligations on the members in their conceptualisation of counterfeiting. *First* it limits the scope to trademarks (*and not IPRs generally*), and, further to trademarks registered in a particular member state. Kenya's apparent over-compliance i.e. TRIPS++ is unwarranted. The limitation accruing from scoping under the Act is also evinced in the implausibility of the ACA's capacity, and technical competence to enforce infringement of the more technical IPRs including patents. It is therefore defeatist, to have a provision improbable to be enforced. Indeed this challenge with the scoping has been successfully challenged in court in the past;<sup>98</sup> as it effectively would proscribe generic medicines which are in every respect different from counterfeit medicine and pharmaceuticals in general. In *P.A.O & 2 Others V A.G (2012) eKLR* the Courts had opportunity to consider the effect of the definition of Counterfeit under Section 2, of the Act and offences created under Sections 32 and 34 of the Act. The Court found that the definition significantly compromised the right to health as enshrined under **Article 43 of the Constitution**. The court subsequently declared unconstitutional sections 2, 32 and 34 of the Act to the extent that it defined counterfeit to extend to IPRs registered in Kenya and elsewhere. The Act was amended to give effect to this determination.

Significantly, this case highlighted the limitation imposed on enforcement of IPRs through counterfeiting, under a broadened definition, certainly extending over and above the country's obligations under TRIPS. Curiously however, the recent amendments by the Kenyan Parliament *vide Statute Law (Misc Amendment) No 18 of 2018* has redefined counterfeit to the very definition that had been declared unconstitutional!

On organs established under the Act, and in addition to the Authority proper, the Act establishes the Authority's Board which is appointed the Cabinet Secretary and consisting of the Principal Secretary in the Ministry of Trade, the Principal Secretary in the Ministry of Trade, the Attorney General, the Commissioner General Kenya Revenue Authority, Managing Director Kenya Bureau of Standards, and the Chief Executive Officer Kenya Association of Manufacturers and two members with 10 years' experience in Counterfeiting or Intellectual Property, Consumer Protection and Trade.<sup>99</sup> The Board's main role is the formulation of policies for organization, management, implementation of objects of the Agency.

It is important to note that the Act equally creates the Intellectual Property Enforcement Coordination & Advisory Committee (IPECAC).<sup>100</sup> IPECACs membership though undefined in law, would essentially comprise the same 14 members as the board, the Act also fails to define particular roles for this organ as set-out in law, this is a zero-sum-game.

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<sup>98</sup> PAO & 2 Others V AG and Another (2014) eKLR.

<sup>99</sup>Section 6, Anti-Counterfeit Act, 2008.

<sup>100</sup>Section 16(4), Anti-Counterfeit Act, 2008.

Additionally, the Act establishes the office of the executive director, which aside from serving as the administrative head for the Authority, this office is also conferred with authority under the Act to record confessions from suspected counterfeiters and issue fines without the option of an appeal. This poses an enforcement challenge, in light of the absence of a defined procedure in law, on the recording of the confessions - contrast these lacunae with the Criminal Procedure Code, CAP 75 which has an elaborate process of recordal of confessions. Worse still no appellate mechanism from the decisions of the executive director is availed in law: exposing the system to possible abuse and/or manipulation.

Further under Section 22 of the Act, the Board appoints inspectors to carry out the ACA's functions who have police powers in their duties under the Act. The appointment of inspectors has to be gazetted, which confers wide ranging powers including entering, seizure, detention, destruction or any other reasonable measures where they suspect that there is production of counterfeit goods. These inspectors include pretty much everyone in IP administration in Kenya, and, minded of expanded the expanded scoping and broad powers of inspectors this would pose a challenge on the efficacy on the enforcement.

Importantly, newly introduced under Section 23, the Statute Law (Misc. Amendment), 2018 the Act expands the mandate of the anti-counterfeit inspectors to *inter alia*, "(4) power to investigate any offence related or connected to counterfeiting notwithstanding that such an offence is not expressed as such under the provisions of this Act." This *carte blanche* is most curious to the extent that an inspector can investigate an 'offence' not expressed as such in law, what would be the consequence of preferring a charge on an offence not defined as such in law? what would be the utility of expending resources on a charge that cannot stand in law? Is the amendment purporting to vitiate a well settled principle on proffering criminal charges, to strictly an offence proscribed by statute, with the penalty similarly set-out thereunder.

Further, (*on the powers of the ACA inspectors*) the amended law, now obligates an ACA inspector to necessarily first procure a warrant to allow them entry to premises suspected to have counterfeit goods, obtained before a magistrate<sup>101</sup>. It allows the inspectors to access the premises even in absence of the owner, but under the authority of the Court. This qualifies the inspectors' powers which earlier allowed them to undertake seizure raids whenever a complaint was lodged with the ACA without prior requiring warrants.<sup>102</sup>

Part IV of the Act deals with counterfeit goods and defines offences in counterfeiting to be those of possession, manufacturing, sell/hire out, exposition, exportation, importation and disposal of counterfeit goods.<sup>103</sup> Any intellectual property holder (*now IPRs subsisting in Kenya or elsewhere*) can lodge a complaint with the Executive Director of the ACA for offences under this Part at Section 32 as long as they can demonstrate that they are entitled to lay the said claim, i.e. that the goods in question are protected goods as well as that there prima

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<sup>101</sup>Section 23(6) and (7), Anti-Counterfeit Act, 2008.

<sup>102</sup>Section 23(1)(a), Anti-Counterfeit Act, 2008.

<sup>103</sup>Section 32, Anti-Counterfeit Act, 2008.

facie exists an intellectual property, with a reasonable suspicion that there may be an offence under Section 32 that has been committed.

Significantly the Kenyan law at Section 32(f) proscribes, ‘import into, transit through, transship within or export from Kenya, except for private and domestic use of the importer or exporter as the case may be, any counterfeit goods’. This provision is designed to insulate Kenya as a transport-corridor for counterfeit goods. In *Panyahululu Limited V Anti-Counterfeit Agency & Another and Societe Bic High Court Mombasa Pet 59 of 2013*, the Courts had opportunity to consider the seizure of suspected counterfeit products trans-shipped through Kenya. In this suit the Anti-Counterfeit Authority had seized a consignment of ball-point pens, suspected to be counterfeit bearing (*without authorization in the course of trade*) the “Bic” Trademark registered in Kenya. The consignment was nonetheless destined for Uganda, (where the “Bic” trademark was supposedly not registered) through the port of Mombasa.

The ACA had sought to prosecute the Petitioners in a criminal case and the Petitioners lodged this constitutional petition challenging the propriety of the charges against it and sought to bar the ACA from proffering the charges against it. In fact, the Petitioner additionally argued that the interested party had unsuccessfully challenged the Petitioner’s use of the interested party’s “Bic” registered trademark in Uganda where the goods were destined, and as such there was no premise to detain the consignment in Kenya.

The court disallowed the Petition finding that the ACA was justified to seize the suspected counterfeit consignment, on account of unauthorized user of a trademark registered in Kenya. The case highlights the Court’s interpretation of the mandate of the ACA to seize suspected counterfeit goods on trans-shipment.

The Act further outlines the process of prosecuting suspected counterfeited goods under Section 34, but also importantly sets-out the powers of the Commissioner of Customs (which powers under the amendment law are equally disjunctively vested in the Executive Director and either of them can exercise these powers) in enforcement of suspected counterfeit goods at Kenya’s points of entry.

The courts separately in *Criminal Case No. 2762 of 2011 (Makadara)*, *The Republic vs Fang Jiawei and Saiyili* discharged the accused persons, Fang Jiawei and Saiyi Li, who had been charged with the offence of being in possession on the course of trade counterfeit goods contrary to section 32(2) as read with S. 35(1) of the Anti-Counterfeit Act 2008. However, the prosecution could not secure a conviction because they had failed to follow the procedure set out under the Act including specifically execution of the inventory of the seized goods, which would evince what was seized from the suspects.

The Act prescribes various penalties under Section 35, of the Act including that a person convicted of counterfeiting is liable for a 5year imprisonment, or, in respect of each article/item involved in the particular act to which offence related a fine of not less than 3 times the retail

price, or both a custodial sentence and a fine. On second/ subsequent conviction, a person convicted is liable for a 15year imprisonment, or, in respect of each article/item involved in the particular act to which offence related a fine not less than 15 times the retail price or both. It has been argued that the Anti-Counterfeit Act does not provide for a mandatory custodial sentence irrespective of the flagrancy of the counterfeiting offence neither does it provides for minimum penalties thus leaving a lot of discretion to the court.<sup>104</sup> Such necessarily enables offenders to get off with light sentences.

Section 27, of the Act empowers the Court to issue an Order of destruction where the seized goods are proven to be counterfeits. In **Criminal Case No. 3268 of 2014; of Republic vs Ahmed Hassan** the accused person, Ahmed Hassan was charged with 4 counts of having in possession, in the course of trade, counterfeit goods, contrary to section 32(a) and 35 (1) of the Anti-Counterfeit Act, 2008, Laws of Kenya. Though the goods were indeed found to be counterfeit, the accused person was acquitted on the basis that no linkage of ownership between the said counterfeit goods and the accused, was established. However, in determining the matter the court gave an order for the counterfeit goods to be destroyed in accordance with Section 28 (3) of the Anti-Counterfeit Act. Highlighting the ACA's jurisdiction to counterfeit goods whether or not an accused person is convicted or acquitted.

Also, the Act under Section 24 proscribes an offense of a person wilfully distracting or obstructing an ACA inspector from discharging his duties, and breaking of a seal or removal of documents sealed off by an inspector or detained at a counterfeit depot.

Further, the Act enjoins the inspectors to respect the IPRs of 'suspected counterfeiters' under, Section 31 of the Act, by providing that, "a person commits an offence if any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of powers of entry conferred on him under this Act; or, any information obtained by him in the performance of functions under this Act." However, this section provides an exception where the disclosure was meant for the purposes of the performance of their duties under this Act.<sup>105</sup> Essentially safeguarding that which is otherwise not illegal but still proprietary to the suspected counterfeiter.

### ***2.2.1(a) The Anti-Counterfeiting Regulations, 2010***

Established by virtue of Section 37 of the Anti-Counterfeiting Act under Legal Notice No. 126 of 2010, these regulations are subsidiary regulations aimed at facilitating the enforcement of the provisions of the Act.<sup>106</sup> They provide for formats for various forms against which the Authority's mandate may be invoked, and also the applications obtaining including those of samples for use by intellectual property owners and the Agency. The Regulations help create specificity on the discharge of the ACA's enforcement mandate.

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<sup>104</sup> B.S Ongola, 'Efficacy of Anti-Counterfeiting Laws in Kenya', 2014, 45.

<sup>105</sup>Section 31, Anti-Counterfeit Act, 2008.

<sup>106</sup> Anti- Counterfeiting Regulations, 2010.

Under Regulation 15, an owner of an intellectual property may submit particulars of the same to the Anti- Counterfeit Agency where the Agency maintains a database of the register.<sup>107</sup> Essentially creating an IPR register at ACA. This is significant to highlight since much as the registration might appear to create certainty on the enforcement by ACA easing verification of subsisting IPRs for the inspectors; these duplication exposes potential for conflict especially where the subject IPR has been challenged before the administering entity e.g. KIPI or even KECOBO but that the ACA has in its database the expunged, revoked or effluxed IPR as subsisting.

Section 20 of the Regulations provides that the owner of suspected counterfeit goods who continues to deal or trade in goods of similar description, commits an offence and is liable upon conviction to imprisonment for a term not exceeding six months, or to a fine not exceeding six thousand shillings, or both. The regulations contain all the rules and procedure for handling counterfeit goods, throughout their provisions.

The legal architecture under the Anti-Counterfeit Act is fairly robust, but the highlighted concerns on some of the provisions thereunder are necessarily posing a challenge to the enforcement of IPRs curbing counterfeiting of pharma-products in Kenya.

### ***2.2.2 The World Trade Agreement on Trade Related Aspects of Intellectual Property (TRIPS)***

The Agreement establishing the World Trade Organisation (WTO) contains as Annex 1C the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement came into force in 1996. Kenya, a founding member of the WTO was amongst the first countries to become as signatory to the Agreement, as early as 1995. This Agreement outlines the minimum standards of protection, member states are obliged to enact, concerning IP Rights in the form of copyrights, trademarks, patents, industrial designs, geographical indicators, integrated circuits and trade secrets.<sup>108</sup> In assessing Kenya's compliance with her obligations under TRIPS, regard must be had to the legal regime it has adopted (if at all) vis-à-vis the obligations accruing under the minimum standards set-out under TRIPS.

Article 61 of TRIPS which creates the obligation against which the Anti-Counterfeit Act, 2008 was enacted provides as follows, '*Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of*

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<sup>107</sup> Regulation 15, Anti- Counterfeiting Regulations, 2010.

<sup>108</sup>Maleche A, 'Legislation and Use of TRIPS Agreements' <http://kelinkeny.org/wp-content/uploads/2010/10/LEGISLATION-AND-USE-OF-TRIPS-AGREEMENT-Final.pdf>

*intellectual property rights, in particular where they are committed willfully and on a commercial scale.'*

Indeed, TRIPS does not enjoin member states to criminalize and punish infringement of IPRs other than 'the willful trademark counterfeit' and 'copyright piracy' on 'a commercial scale.' So that even the obligations comes with qualifiers, such that if the intent of an infringer as being willful cannot be established or the counterfeiting not being at a commercial scale, then a law that proscribes to the contrary is TRIPS non-compliant. However, in including other IPRs within the scope of counterfeits as Kenya has done, the same is not violation of TRIPS it allows members discretion to so do, again with qualifiers on 'willful counterfeiting' and 'commercial scale' but in light of the challenge such a broad conceptualization causes on efficiency of enforcement and the direct threat it causes on right to health on access to medicine through generics there can be little value in over-compliance.

Further under TRIPS, all member states are required to ensure that their national legislation reflects the provisions in the Agreement to ensure enforcement of the same. Specifically, on counterfeiting footnote 14 to Article 61 of the TRIPS Agreement provides the following: "*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;*"

Importantly trademark counterfeiting differs from trademark infringement, in light of the provisions of Article 61 as read with footnote 14, which the WTO advises is essential in understanding the acts, for which the penal sanctions apply. These would be 'willful', 'unauthorized user of a trademark' and 'at a commercial scale'.<sup>109</sup>

This definition of counterfeit under TRIPS, not only excludes other IP rights obtaining in pharma such as patents, and limit the scope to trademarks; but also, TRIPS appears to observe the territoriality of IPRs. It additionally recognizes the protection of trademarks obtaining in the country of importation and not 'elsewhere'. The Kenyan law measured against this TRIPS' minimum standard is therefore said to be TRIPS++. The over compliance necessarily obfuscates enforcement by stretching the limited resources to enforce what is already exempt.

Countries like the USA, which have a high level of patent protection have omitted patents from this conceptualisation, as permitted by TRIPS. In the USA criminal penalties are available for intentionally dealing in goods or services knowingly using a counterfeit mark.<sup>110</sup> In explaining the cause of the variance, it is acknowledged that due to differences in enforcement rules in

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<sup>109</sup> WTO Analytical Index, TRIPS Agreement-Article 61 Jurisprudence accessed at [https://www.wto.org/english/res\\_e/publications\\_e/ai17\\_e/trips\\_art61\\_jur.pdf](https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art61_jur.pdf)

<sup>110</sup> ICISP-UNCTAD Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement (2004), at page 620

different national legal systems and the difficulty to harmonise the enforcement rules; a compromise was struck to adopt a ‘result-oriented’ approach being to prevent infringement rather than agree on specific obligations. This lacuna created room for the TRIPS++ compliance. In any event it is acknowledged that the push for ‘consensus’ on essential elements of enforcement procedures, was bulldozed by the USA and EC reflecting views of their business community; with developing countries only just able to avoid obligation to establish specialised judicial system on enforcement.<sup>111</sup>

### 2.2.3 Penal Code

Further the Kenyan Penal Code<sup>112</sup>, also addresses itself to help curbing counterfeit pharma products. Specifically, under Section 243(e) and (f) the law criminalises counterfeiting of pharmaceutical products and provide thus:

“Any person who, in a manner so rash or negligent as to endanger human life or to be likely to cause harm to any other

- (e) gives medical or surgical treatment to any person whom he has undertaken to treat; or,
- (f) dispenses, supplies, sells, administers or gives away any medicine or poisonous or dangerous matter ... is guilty of a misdemeanour.”

This provision further avails additional proscription under the law, as against availing for sale counterfeit pharma. In curbing counterfeiting of pharma, the law enforcement agencies may adopt these provisions.

### 2.2.4 Pharmacy & Poisons Act

The Pharmacy & Poisons Act in its preamble has been described as, “an Act of Parliament to make better provision for the control of the profession of pharmacy and the trade in drugs and poisons.”<sup>113</sup> Section 3 of the Act establishes the Pharmacy & Poisons Boards (PPB) whose functions include: *assessing the nature and extent of counterfeit drugs*, strengthening the effectiveness of drug regulating authorities, the review and strengthening of legislation relating to pharmaceutical products as well strengthen enforcement in investigation, prosecution, conviction of offences and collaboration at national, regional and international levels. It also trains staff on drug regulating authorities, customs and law enforcement agencies establish import procedures-designate specific ports of entry, quarantine for suspected drugs.

A distinction however subsists on the quality of the product as well as pharmacovigilance *vis-à-vis* whether or not such product is counterfeit. The considerations are varied and the counterfeit does not necessarily concern the quality or effects of pharmaceutical products, but rather the unauthorised user of the pharma-IPRs in a commercial context. As such the larger

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<sup>111</sup> ICISP-UNCTAD Resource Book on TRIPS and Development, 578 and 579

<sup>112</sup> Penal Code, CAP 63 Laws of Kenya

<sup>113</sup> Pharmacy and Poisons Act, CAP 244, Laws of Kenya.

mandate of the PPB on examination and testing is outside the ambit of this paper. In an interview with the Nation Newspaper on what the board was doing in the fight against pharma counterfeits, Dr. Fred Siyoi the then Director of the Pharmacy and Poisons Board said that the board was raising public awareness campaigns on counterfeit drugs, carrying out routine inspections as well as ensuring that all registered products were available on the board's website and that products were thoroughly vetted and entry points for drugs gazetted. He also noted that there was 24-hour surveillance in borders as well as usage of the Raman Spectrometer which is a device used to screen drugs and can detect the counterfeits. He also added that the board was collaborating with Interpol, the WHO on the fights against counterfeit medicines<sup>114</sup> Nonetheless in discharge of its role under Section 3 of the Act, the PPB has equally been engaged in combating counterfeit pharma. Dr Siyoi also reported that Kenyans would soon be able to use their mobile phones to identify whether the medicines they take are genuine through a short message code which was undergoing testing and set to be rolled out in mid-2019. Further, that the Board was working with software developers to create a unique code that will be used to identify the quality as well as track across the supply chain all medicines in the country — imported or locally manufactured<sup>115</sup>

Although it has been reported that since 2016, PPB has closed more than 670 illegal pharmaceutical outlets across the country and consequently 612 persons arraigned in Court over operating illegal pharmacies, the Board has never published any of its reports in connection with its efforts on counterfeiting which raises a lot of speculation on how rampant is the situation and whether at all actual progress is being made.<sup>116</sup> It may well be an acknowledgment that such falls outside their ambit but more accurately their exercise of their mandate necessarily collects this data, which they ought to publish.

#### **2.2.4(a) Guidelines for Good Distribution Practices for Pharmaceuticals, 2006**

These guidelines were developed pursuant to the provisions of the Pharmacy and Poisons Act, to guide licensees on distribution of pharmaceuticals, both wholesale and retail. The guidelines are meant to provide persons involved or wishing to be involved in pharmaceutical distribution with a method of assessing eligibility and the process of lawfully operating drug distribution outlets.<sup>117</sup>

In particular, part 10 of these guidelines gives provisions for the handling of counterfeit goods. It states that Products which are suspected to be counterfeit should be kept in a designated

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<sup>114</sup> Collins Omulo 'Board to take its war on fake drugs mobile', 6 February 2019.

<<https://mobile.nation.co.ke/news/War-on-counterfeit-medicines-goes-mobile/1950946-4969690-/index.html>> on 13 April 2019,

<sup>115</sup> Collins Omulo 'Board to take its war on fake drugs mobile'.

<sup>116</sup> Stella Murumba, 'How potentially lethal fake drugs get into African countries including Kenya' <<https://www.businessdailyafrica.com/economy/INDEPTH--How-deadly-fake-drugs-get-into-Kenya---VIDEO/3946234-4003050-csc2apz/index.html>> accessed 13 April 2019

<sup>117</sup> <<https://infotradekenya.go.ke/media/Guidelines%20For%20Good%20Distribution%20Practices%20for%20Pharmaceuticals.pdf>> accessed 12 April 2019.

area apart from other medicinal products to avoid confusion. It further states that they should be clearly labelled as “NOT FOR SALE”. Further the guidelines require the handler of the said goods to inform the Pharmacy and Poisons Board and the holder of the products registration.<sup>118</sup>

### **2.2.5 *The Kenya Revenue Authority Act, 1995***

This paper presumes that one of the biggest effects of counterfeiting and in this respect pharma counterfeiting is that it leads to great loss of revenue collection by the government. According to the Kenya Revenue Authority, counterfeiting costs the Government of Kenya shillings 6 billion (about \$ 84 million) in lost revenue annually.<sup>119</sup>

The Kenya Revenue being Kenya’s taxman primarily discharges the function of revenue collection in Kenya as well as customs authorities play an important role in the fight against counterfeit and pirated products. Counterfeiters take advantage of countries where there are weak enforcements and laws on intellectual property as their haven for production. They then export the goods produced to countries where there is a high demand for the goods and this has necessitated border measures in the fight against counterfeiting.<sup>120</sup>

Therefore, the Kenya Revenue Authority plays a crucial role to this extent noting that over the years there has been a global increase in cross border trade. Customs officers can seize and destroy goods that are prohibited goods, either under the Customs Act, or which are illegal under any other Act, which makes them prohibited under Customs.<sup>121</sup>

The Anti-Counterfeit Act afore-discussed vests certain shared mandates with the Commissioner for customs (an office established under the Kenya Revenue Authority Act No 2of 1995) on seizure of counterfeit products at points of entry.

### **2.2.6 *East African Community Competition Act, 2006***

This Act was established to promote and protect fair competition in the East African Community which comprises of seven member states, to provide for consumer welfare, to establish the East African Community Competition Authority and for related matters. Some amendments were made in this Act to allow for the protection of Trademarks and copyrights only but not patents.<sup>122</sup> Significantly one of the amendments provides that its provisions shall not be construed as prohibiting the manufacture, importation, sale or dealing in medicinal

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<sup>118</sup> *ibid.*

<sup>119</sup> Keynote Address By Honourable Amos Wako, Attorney General Of Kenya, During The Third Global Congress On Combating Counterfeiting And Piracy At The International Conference Centre In Geneva, Switzerland On January 30 2007, ‘Promoting Better Legislation And Enforcement Of Intellectual Property Rights In Kenya’

<sup>120</sup>[https://www.academia.edu/12063417/UNDERSTANDING\\_THE\\_ROLE\\_OF\\_GOVERNMENT\\_DEPARTMENTS\\_I\\_N\\_FIGHTING\\_CONTERFEITS\\_IN\\_KENYA](https://www.academia.edu/12063417/UNDERSTANDING_THE_ROLE_OF_GOVERNMENT_DEPARTMENTS_I_N_FIGHTING_CONTERFEITS_IN_KENYA)

<sup>121</sup>[https://www.academia.edu/12063417/UNDERSTANDING\\_THE\\_ROLE\\_OF\\_GOVERNMENT\\_DEPARTMENTS\\_I\\_N\\_FIGHTING\\_CONTERFEITS\\_IN\\_KENYA](https://www.academia.edu/12063417/UNDERSTANDING_THE_ROLE_OF_GOVERNMENT_DEPARTMENTS_I_N_FIGHTING_CONTERFEITS_IN_KENYA)

<sup>122</sup> < [http://www.eala.org/uploads/The\\_East\\_African\\_Community\\_Competition\\_Amendment\\_Act\\_2010.pdf](http://www.eala.org/uploads/The_East_African_Community_Competition_Amendment_Act_2010.pdf)> accessed 13 March 2019

products generally known as generic medicines, provided that such medicines are not counterfeit goods.<sup>123</sup>

Reference to this law is important as a major concern that must be borne in effectively addressing the fight on counterfeit pharma, is the cross-border nature of this illicit trade. Regional measures would certainly be integral in effectively addressing the issue.

### ***2.2.7 East African Common Market Protocol***

This Protocol was established pursuant to the provisions of articles 76 and 104 of the treaty for the establishment of the East African Community and came into force in the year 2010.<sup>124</sup> Under Article 35 (1) of the Protocol, partner states are bound to ensure that they promote then interests of the members of the Community by ensuring protection of life, health and safety of consumers. Sub-article 2 of the same Article compels states to ensure that they encourage fair and effective competition in order to provide consumers with greater choices in goods at the lowest prices.

Under Article 43 (1), partner states are bound to co-operate in the protection of intellectual property rights through promotion and promotion of creativity for economic, technological and socio-cultural development in the community. More specifically, Article 43(2)(c) partner states agree to cooperate in piracy and counterfeit activities.

## **2.3 Conclusion**

A discussion of the above laws, evinces that indeed Kenya does have an established legal framework on enforcement of counterfeiting. However, the existence of this legal regime, whilst laudable does not equate to an effective enforcement regime. The ineffective enforcement of IP, exposes millions to risk of death through failure to protect public health,<sup>125</sup> but also critically serves to disincentive investment into the pharma-industry which is often costs not just through the R&D, clinical trials and regulatory approvals but also the marketing costs.

In this respect, and informed by the discussions above the current legal framework on curbing pharma-counterfeiting is inadequate negating the value-add from the creation/registration of the IPRs. This paper considers the consequence of these inadequacies in the next chapter, and it will ultimately recommend redress measures in its concluding chapter.

The primary legislation within the Kenyan legal regime on combating counterfeits is the Anti-Counterfeit Act, 2008; which in its enactment must be minded by the minimums required of the country under the TRIPS without unduly encumbering Trade in pharma or worse still

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<sup>123</sup> <[https://unctad.org/en/PublicationsLibrary/diaepcb2015d6\\_en.pdf](https://unctad.org/en/PublicationsLibrary/diaepcb2015d6_en.pdf)>accessed 14 April 2019.

<sup>124</sup> <<http://eacj.org/wp-content/uploads/2012/08/Common-Market-Protocol.pdf>> accessed 13 March 2019

<sup>125</sup> Sell S, The Global IP Upward Ratchet, Anti-counterfeiting and Piracy Enforcement Efforts, 20

encumber the actualization of the right to health. It is noteworthy that Kenya enacted Statute Law (miscellaneous amendment), No 18 of 2018 which law *inter alia* amended the Anti-Counterfeit law, to better enhance the enforcement measures, redefining the enforcement organs and adding onto the power of the ACA including enhancing its capacity as a government authority as opposed to an agency, which also increases their budgetary allocation with a direct impact on ability to actualize programmes.

The preceding discussion on the various laws obtaining in Kenya, enacted variously to curb the proliferation of counterfeit pharmaceuticals evinces that Kenya does not have a limitation of legal enactments geared at fighting counterfeit pharma. The discussion however, also importantly highlights the significant limitations posed by these laws on the efficacy of the country's fight against counterfeit pharma.



### 3.0 Chapter Three: The Effect of Ineffective Enforcement against Counterfeits on the Growth of the Pharmaceutical Industry in Kenya

#### 3.1 A Review of Data and Statistics on Counterfeiting

According to the WHO trade in counterfeit medicine rake sin an average of \$100 Million annually. With the bulk of these being destined and/or otherwise trans-shipped through Africa, and the Port of Mombasa in particular ranked by the UN as a major hub.<sup>126</sup> Worse still the drugs targeted concern medicines for serious ailments, perceivably due to the high costs of the genuine product, unavailability or just plain old-ignorance by the consumers. The WCO in the report by Ms Murumba note that, “13 million illicit and potentially dangerous pharmaceutical products, over 12 million (12,509,823) units were netted at the Mombasa seaport alone.”<sup>127</sup> Quite patently Mombasa and Kenya appears to be a soft target, which must pose questions as to the efficacy of the regimes that we have in place to respond to the challenge.

The number of seizures made in the four operations between 2012 and 2017 reached almost 900 million counterfeit and illicit medicines worth about €400 million (Sh46.2billion), so much so that there is a clear financial impact of the illicit trade, globally but particularly in Kenya and the East African region.<sup>128</sup> But worse still so many lives are lost on account of this trade, WHO estimates that, “... 700,000 people are killed globally by counterfeit medicines annually. Africa contributes 100,000 of these deaths.” Presumably, Kenya contributes a significant number to these deaths noting from the volume of the seizures netted in Kenya.

The WHO also notes that the everyday medicine is particularly targeted but brazenly also, the counterfeiters have worked their nets into lifesaving medicines for ailments such as cancer, HIV/AIDS, cardiovascular and diabetic conditions<sup>129</sup>– without a care. The WHO quotes the Interpol whilst issuing a caveat as to unavailability of enough accurate data on the level of counterfeit medicine, it reports that not less than 50% of the medicines purchased online are counterfeit. Most of which funds finance criminal networks and deprive governments of much needed revenue to provide public service.<sup>130</sup>

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<sup>126</sup>Murumba, S, *Fake China, India Drugs put Kenya at Risk*, Business Daily, on 4 June 2017, <https://www.businessdailyafrica.com/news/Fake-China--India-drugs-put-Kenyans-at-risk/539546-3955666-cls8bo/index.html>.

<sup>127</sup>Murumba, S, *Fake China, India Drugs put Kenya at Risk*.

<sup>128</sup> Murumba S, *Fake China India Drugs put Kenya at Risk*.

<sup>129</sup>Murumba S, ‘Getting a grip on Counterfeit Medicine in Kenya’ <https://medium.com/code-for-africa/getting-a-grip-on-counterfeit-medicine-in-kenya-what-next-d4766660cbfd>.

<sup>130</sup> World Health Organisation, ‘*Growing Threat from Counterfeit Medicines*,’ Bulletin of the World Health Organisation, accessed at <https://www.who.int/bulletin/volumes/88/4/10-020410/en/>

In his 2012 e-publication *Jack's 2012 Faking It*<sup>131</sup>, he studied the scale of proliferation in counterfeit medicine in Kenya, and the observation that reportedly HIV patients in Kenya are affected by Counterfeit ARVs. Vepachedu further highlights the health complications brought about by counterfeit anti-bacterials and highlights that there is an increase in antimicrobial resistance (AMR). The WHO attribute the proliferation in counterfeit medicines to the spread of ARM. The WHO estimates that antimicrobial resistance (AMR) could kill 10 million people per year by 205. Counterfeit medicines have the wrong amount of an active ingredient, none at all, or a different one all of which catalyse the resistance against various pharmaceutical regimes.<sup>132</sup>

Counterfeit medicine is not a uniquely Kenyan (or African challenge) according to the WCO, '... counterfeit medicines are on the rise, and cost the EU pharmaceutical industry €10.2 billion (US \$12.4 billion) a year in lost sales, according to a European Union Intellectual Property Office report with an increased use of e-commerce by the counterfeiters coupled with the difficulty of tracing the source of those selling via these platforms.'<sup>133</sup> As such curbing the menace must have extra-territorial mechanisms including addressing the online marketplace.

The data considered herein though sounds alarmingly high, experts say it barely accurately captures the full extent, and that supposedly the same is a scratch on the surface of an otherwise organised criminal network.

The KBS National Economic Survey, 2019 Report, reporting on the quantity and value of imports and exports of pharmaceutical products over the last five years, evinces a difference of almost 15,000 metric tonnes between the value in imports and exports. The report also captures that the value of imports from India rose from KES 170.4 Billion in 2017 to KES 185.3 Billion in 2018, also evincing a fairly heavy reliance on pharma imports particularly from India.

The data is undeniable as it loudly exposes the size of the problem, counterfeiting certainly not only rakes in tremendously from the illicit trade, but it also denies genuine pharma businesses a fair return on their proprietary rights, and denies governments revenue. Worse still, with this massive scale of illicit trade the significant health risk/exposure for the consumers of the counterfeit pharma is equally disturbingly high.

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<sup>131</sup> Jack A, 'Faking It'.

<sup>132</sup>Vepachedu R, 'COUNTERFEIT MEDICINES - Code Red now to RACE'.

<sup>133</sup> Vepachedu R, 'COUNTERFEIT MEDICINES - Code Red now to RACE'.

The ICC, urges that this unabated escalation of the illicit trade has a domino effect outside the obvious infringement and violation of proprietary rights.<sup>134</sup> It cautions that this illicit trade will lead to closure of pharma business, consequent unemployment, availability for funding for organized crime and ultimately possible brake down of law of order. The losses sustained by industry will equally be reflected in losses to the public revenue.

Sell however disputes the startling data on proliferation levels, she cautions that the evidence of counterfeit drugs is anecdotal rather than empirical. This is because the only global collection point for the ‘raw’ data on counterfeit drugs is the Pharmaceutical Security Institute – constituting 14 global drug companies, who never release such data publicly.<sup>135</sup> She decries that the limited data is one sided and, of course, favour the rights holders.

### 3.2 Pharma-Counterfeiting, and the Growth of Genuine Pharma-Industry

As a preliminary, it this paper’s argument that intellectual property and particularly responsive enforcement of intellectual property necessarily positively impacts trade (*both domestic and international*), licit competition, manufacturing and industrial growth and ultimately socio-economic development.<sup>136</sup> Without an apt anti-counterfeiting legal system then the consequence is a stunted and receding growth of the genuine pharma industry, as well as a dereliction of the duty to safeguard patients’ right to access healthcare. Further, a report published by a taskforce established under Kenya’s MoH<sup>137</sup> rightly notes that, Counterfeit-pharma are a major problem globally and Kenya is equally fair-game. It cautions on the major adverse impact the counterfeits have on public health. They worrisomely add that it is a lot worse and the problem even more pronounced in a situation where the manufacture, importation, distribution, supply and sell of medicines are less regulated and enforcement mechanism is weak.

Luccini reports that, “The predicted **growth** in the global pharma-market between 2012 and 2021 is **estimated at 26%**, (according to PROPARCO’s SP & D publication), but the African drug market **could increase by 200% according to a realistic assumption**, or by **300% according** to an optimistic hypothesis within this same period. Based on African Pharma-Market Report of Frost and Sullivan of 2016, the pharma-market in Africa is expected to reach a business opportunity of **\$45 billion in 2020**. Goldstein Research analyst forecast the Africa

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<sup>134</sup> ICC-CIB, ‘Getting a feel of the problem’, 11.

<sup>135</sup> Sell S, The Global IP Upward Ratchet, Anti-counterfeiting and Piracy Enforcement Efforts, 18

<sup>136</sup> Sikoyo G, et al, ‘Intellectual Property Protection in Africa’.

<sup>137</sup> Pharmacy and Poisons Board, *Task-Force Report on Parallel Importation, Counterfeits and Illegal Trade in Pharmaceuticals*, Ministry of Health <http://apps.who.int/medicinedocs/documents/s21359en/s21359en.pdf>

pharma-market size is set to reach **USD 160.7 billion by 2024**, at a CAGR of 20.4% over the forecast years.”<sup>138</sup> Staggering business prospects.

Contemporaneous thereto, is the report by the WHO that proportional contribution of Non-Communicable Diseases (NCD) to the healthcare burden in Africa will rise by 21% through 2030. Luccini’s report also highlights that, “the tropical climate of Africa makes the continent the **largest reservoir of infectious diseases**, particularly malaria, tuberculosis (TB), and acquired immune deficiency syndrome (AIDS), besides frequent outbreaks of polio, meningitis, cholera, pandemic influenza, yellow fever, measles, hepatitis, and tetanus. With the increasing adoption of Western lifestyle in Africa, there has been a **paradigm shift in the burden of illness towards non-communicable diseases** (NCDs), driving the demand for chronic prescription drugs.”<sup>139</sup> On the strength of these reports then in terms of growth, it is projected that the global and African pharma markets are positioned on a growth trajectory. However how is Kenya’s anti-counterfeiting legal system positioning it to reap from this prediction. Undeniably there is an increase in the chronic illness as reported by Lucchini, but also the tropical illness have far too long raved its citizen’s. Wouldn’t a responsive review of the enforcement against counterfeiting increase the drive to establish a more robust pharma-industry for Kenya or is the current regime responsive enough.

Dent records that, proponents of stricter IP legal system, (such as the approach seemingly adopted by Kenya) urge that IP must be protected at all costs. But even more centrally, these proponents urge that without strong IP protection innovative products would no longer be made or availed to the greater ‘publics.’<sup>140</sup> Dent also acknowledges that counterfeiters set-out, “to make the product or service look like an original, whether to fool consumers into buying it, or to allow the consumer to fool others into thinking that they bought the real deal.”<sup>141</sup>

### ***3.2.1 Drivers of Counterfeiting, and their effect on Growth of Pharma-Industry***

An interesting exposition from Dent is that he helps identify a useful key dichotomy in drivers of counterfeit with reference to the complicit consumer of the one hand, and the unscrupulous merchant of the other. Such that in understanding the specificities of what drives pharma-counterfeits it must be critiqued from the spectrum of these two classes.

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<sup>138</sup>Lucchini C, African Pharmaceutical Market, PharmaWorld Magazine, 30<sup>th</sup> November, 2018 <https://www.pharmaworldmagazine.com/african-pharmaceutical-market/>.

<sup>139</sup>Lucchini C, African Pharmaceutical Market.

<sup>140</sup> Dent AS, Intellectual Property, Piracy, and Counterfeiting, 2016, Reviews in Advance, The George Washington University.

<sup>141</sup> Dent AS, Intellectual Property, Piracy, and Counterfeiting.

The success of counterfeit trade is structured of the one hand ‘consumer accomplices’ who knowingly set-out to and proceed to purchase counterfeits: and contemporaneously ‘illicit merchants’ who knowingly put up for sale counterfeit products either for varied premises. Sihanya cites that Kenyans reportedly prefer counterfeit products due to their general affordability, that allows access to goods the preserve of middle and upper classes.<sup>142</sup>

Bloch, Peter H et al explores this demand side of the counterfeiting spectra, and introduces the term Consumer Accomplices in product counterfeiting. He notes that some consumers are complicit – knowingly purchasing/creating a market for counterfeits. This lending credence to the premise for segregation of counterfeit drivers, in developing an apt understanding of the counterfeiting problem. In enhancing efficacy of fight against counterfeits, adequate concern must be directed at redressing the segregated driver of consumer complicity, of the one part.

Differing from Dent, Bloch et al urge that the consumer accomplices are drawn to counterfeits on account of the availability of the counterfeits i.e. the counterfeits are better distributed and more readily available than the genuine products. But even more particularly, Bloch et al observe that the counterfeits are often better priced than the genuine products. As afore-cited in this paper, these consumer accomplices drive counterfeiting on account of their comparative affordability, convenience and accessibility and availability.<sup>143</sup> Nayarah Siva similarly urges<sup>144</sup> that the often prohibitive costs of genuine pharma-products fuels the growth of counterfeit-pharma. He cautions that counterfeiters are extremely flexible in their approaches, making their dangerous products readily available to the unwitting consumers. Nonetheless it is Siva’s view that effective anti-counterfeit measures will lower the costs of genuine pharma-products.

A United Nation’s 2016 report<sup>145</sup> similarly, notes that the prices for genuine medicines in Kenya and the East African Community, are often out of reach for developing countries' public health systems. Critically the UN notes that this high prices largely accrue due to the IPRs held over these drugs, which IPRs exclude access, and competition from reasonably priced generics. Indeed even the Doha talks, acknowledged the impact IPR protection has on potentially lessening access and affordability of medicines but also acknowledged importance of IPR in incentivising R&D into new medicines.<sup>146</sup> The architecture of the legal system which protects

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<sup>142</sup>Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 472.

<sup>143</sup>Bloch P, et al "Consumer “accomplices””.

<sup>144</sup> Siva N, ‘Tackling the booming trade in Counterfeit Drugs’.

<sup>145</sup>The United Nations Conference on Trade and Development-United Nations Industrial Development Organisation, ‘TRIPS Flexibilities and Anti-Counterfeit Legislation in Kenya and the EAC: Implications for Generic Producers’ 2016.

<sup>146</sup>Declaration on the TRIPS Agreement and Public Health, WTO document WT/MIN(01)/DEC/W/2, of 14 November 2001. Available at: <http://www.who.int/medicines/areas/policy/tripshealth.pdf>.

IPRs in pharma-products, therefore must be minded to balance the three converging interests of intellectual property rights holder, competition and consumer protection.

Blakeney equally addresses the consumer accomplice phenomena, by observing that counterfeiting would actually be non-existent without the consumer demand for the counterfeits, and the misconception of counterfeiting as not crimes per se but innocuous infractions.<sup>147</sup> Blakeney identifies the conceptualisation of what amounts to counterfeits are in the eyes of the law as a factor in the growth of counterfeit in pharma.

The other spectra of the first limb espoused in Dent's exposition is the supply-side from the illicit merchants who seek to cash in on trying to make their products look real. Their motivation is a lot more uncomplicated with focus being to simply ride on the good will of the better known branded products. Profit motivation is quite simply the driver on this limb.

The second core driver of counterfeiting, as evinced in Dent's exposition is the challenge of wilful infringement by illicit merchants who focus on the look or resemblance to the real/genuine. Underscoring the need for protection of trademarks in curbing counterfeiting. Dent criticizes what he describes as an attempt by certain players to reap maximum possible from anti-counterfeiting measures, by seeking to unify IP violations under one rubric. He importantly cautions that this unification threatens even perfectly legal generic drugs into the ambit of counterfeit. He urges that, "... (unification) grouping tactics are also frequently useful in persuading local law enforcement agencies to police the strict rules that are so often on the books, even in developing economies where such policing is potentially counterproductive".<sup>148</sup>

Sell, equally raises a similar concern by cautioning against the 'IP Maximalists' out to assert rights without obligations, using the TRIPs obligations as the floor and not ceiling. There is an apparent attempt to drive broader, wider and higher IPR protection through a global anti-counterfeiting initiative. Sell cautions that most developing countries adopt TRIPs plus plus measures, unwarrantedly self-imposing much higher levels of protection which have the effect of negating access to health. Importantly, the broadened conceptualisation of counterfeits and failure to limit pharma-counterfeits to those wilfully infringing on trademark rights, unwittingly criminalises behaviour that is otherwise legal including compulsory licensing, parallel importation and generics.<sup>149</sup>

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<sup>147</sup>Blakeney M, Counterfeiting and Piracy: An Overview'.

<sup>148</sup>Dent AS, Intellectual Property, Piracy, and Counterfeiting.

<sup>149</sup>Sell S, The Global IP Upward Ratchet, Anti-counterfeiting and Piracy Enforcement Efforts, 15.

Parallel importation involves the sale of pharma-products that are often genuine, often identical to legitimate products except that they may be packaged differently and may not carry the original manufacturer's warranty. Parallel importation involves importation of goods from countries of manufacture of first sale, usually without authority of IPR owner. The trade in generics is an off-shoot of parallel importation as reproduction of drugs is much cheaper than actually researching on and developing or manufacturing the first unit.<sup>150</sup> Article 6 of TRIPS defers regulation of parallel imports to national laws, allowing member states to align their IPR enforcement legal system against counterfeits to the reasonable treatment of generics. A broadened conceptualisation of counterfeits may unduly extend to parallel exports.

Part III of the TRIPs agreement, enjoins the member states to establish border measures and criminal sanctions that are binding in relation to Trademarks and Copyright only, though members would retain discretion for higher levels of protection and extension to other IPRs.<sup>151</sup> Such that criminal sanctions exposed through anti-counterfeiting laws are only mandatory, in response to wilful trademark counterfeiting.<sup>152</sup> The TRIPS expressly excludes through admissible exceptions,<sup>153</sup> including compulsory licensing from conceptualisation as counterfeit, recognising need for a tapered approach to not unduly negate right to health erstwhile promoting innovation and licit trade. Sell urges for a need for clarity and defined scoping through apt terminology to distinguish and create rules that do not criminalise pharma-products lawfully produced under TRIPS compliant rules including grey goods and generics.<sup>154</sup>

Indeed, this exposition highlights the limitation posed on curbing counterfeiting as a result of an inefficacious approach through a broadened conceptualisation of counterfeits. If Kenya's approaches are not localized, and continue imposing IP maximalist approaches, would be ill-suited to curbing the growth of pharma-counterfeit.

Abdul Sattar and Tahir Mahmud, undertook an extensive review of empirical studies critiquing the impact (if any) of IPR Protection and economic development. Against the background of the effect of enhanced IPR protection in Pakistan, they urge that effective protection of IPR necessarily bring about greater innovation, with an assured return on the research and development for the innovators and a direct consequence on socio-economic development. This is because the innovators are assured of an opportunity to recoup from their innovation. Importantly they highlight that countries at lower levels of development coincidentally have

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<sup>150</sup>Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 438 and 442.

<sup>151</sup> ICISP-UNCTAD Capacity Building Project on IPRs and Sustainable Development: Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement, 2004.

<sup>152</sup> ICISP-UNCTAD Capacity Building Project on IPRs and Sustainable Development, 576.

<sup>153</sup> Articles 13 and 30, TRIPS Agreement.

<sup>154</sup>Sell S, The Global IP Upward Ratchet, Anti-counterfeiting and Piracy Enforcement Efforts, 20.

weaker forms of IPR protection, whereas high income (developed) countries have stronger IPR protection regimes.<sup>155</sup> Against a legal regime assuring of return on investment, incentives accrue to employ resources in the endeavour of innovation.

Sattar and Mahmood considered the impact of recognition and enforcement of IPRs, on economic growth from a sample of thirty-eight (38) countries categorized at different levels of development including 11, high income countries; 16, middle income countries; and 11, low income countries, over the period of thirty years i.e. from 1975-2005 by utilizing Ginarte and Park Index of Intellectual Property Rights (2005). The overwhelming conclusion over this study is that IPR recognition and protection plays a significant role in economic development. They however qualify this by observing that for developed and developing countries the impact is a lot more apparent than for least developed countries. This may be attributable to the oft unenforced or non-existent IPR regimes in the lower spectrum of developed vis-à-vis developing countries. Sihanya acknowledging the nexus between IP and levels of development notes that undeveloped or weak IP legal systems are usually a consequence of the level of industrial development. This he explains by noting that as a natural path, undeveloped economies encourage liberal access to foreign IPRs but as the domestic industries grow and generate their own IPRs, these industries lobby for stronger protection from their governments, and ultimately the level of protection is enhanced.<sup>156</sup>

On an extensive empirical review of the nexus between IPR protection and economic development Ginarte and Park (1997) have developed an index of 110 countries,<sup>157</sup> being an un-weighted index of five separate scores focusing on first, coverage i.e. the scope of protection available in a particular country; second, membership in international treaties; third, duration of protection (and or validity period of protection); fourth, enforcement mechanisms; and fifth, restrictions imposed including compulsory licensing inter alia.<sup>158</sup> The study by Ginarte and Park, (updated in 2005) while focusing on patents, importantly established inter alia that the developed countries have stronger protection of IPRs which often translates to a long term stimulus to production. Further this research established that developing countries often have a low level of research coupled with disinterest in enforcement of intellectual property rights

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<sup>155</sup> Sattar A and Mahmood T, Intellectual Property Rights and Economic Growth: Evidences from High, Middle and Low Income Countries *Pakistan Economic and Social Review* Volume 49, No. 2, Winter 2011, 163-186.

<sup>156</sup> Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 463 quoting Frank Emmert 'Intellectual Property in the Uruguayan Round – Negotiating Strategies of the Western Industrialized Countries', 1990, Vol. II Michigan Journal of International Law, 1317 – 1379.

<sup>157</sup> Ginarte JC and Park WG, Determinants of patent rights: A cross-national study. *Research policy*, 26(3), (1997) 283-301 on [https://www.copyrightevidence.org/evidence-wiki/index.php/Ginarte\\_and\\_Park\\_\(1997\)](https://www.copyrightevidence.org/evidence-wiki/index.php/Ginarte_and_Park_(1997))

<sup>158</sup> Park GW, International patent protection 1960-2005, 10 March 2008, Elsevier BV, on [http://fs2.american.edu/wgp/www/res\\_policy08.pdf](http://fs2.american.edu/wgp/www/res_policy08.pdf)

from these governments; essentially that low research levels de-incentivized protection and enforcement of IPRs.

In adopting effective IPR protection, the study by Sattar and Mahmood similarly evinces that the developed economies are incentivized to enhance the level of protection on account of the innovative capacities in these countries but also the market size targeted for the exploitation of their protected IPRs. So that, it is cyclic that the IPR protection almost self-incentivizes i.e. the benefit of enhancing protection is more real as the actual protection is accorded.

Sell retorts that there is a deliberate ‘use of misleading data and rhetoric’ and hyperbolic equation of counterfeiting to human, drugs and small arms trafficking as well as black market trade in nuclear. She urges that this is used by industry lobbyist to push for IP maximalist laws and drive higher prices and profits for pharma-business.

Contemporaneously, in isolating the effects of illicit trade, it is urged that apt enforcement against counterfeits may not have any impact of the growth of pharma industry and industry generally. Sell notes that high production costs absent subsidies may still hamper growth. Sikoyo G et al note<sup>159</sup> that use of apt IPR enforcement may be used to incentivize innovation and invention, as it avails a mechanism for market protection. The bigger pharma business with years and massive investments in R&D can exploit this protection, perhaps at great costs to locals who may be unable to afford the only genuine available pharma product.

Sikoyo G, et al, similarly observe that strengthened IPR protection will disenfranchise its use for technological innovation, and the costs of accessing the IPRs and/or emerging technologies connected thereto will increase, and as such the growth of the pharma industry will be curtailed.

A permissive environment for counterfeits through supposed as convenient for developing economies, may indeed result to short-term gains including ease access to and transfer of technology and pharma-products that were otherwise out of reach, possibly increase business opportunities, create employment or even save forex that would have been spent on importing the technology and have this funds applied elsewhere: but long term the losses are massive.<sup>160</sup> The huge negative effects have been highlighted elsewhere in this paper. Sihanya cautions that in addition to the negative effects which outweigh the fallacious benefits of a permissive environment; these short term gains fails to incentivise endogenous technological capability, fails to nature an IP culture and respect for endogenous culture and in any event the most

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<sup>159</sup> Sikoyo G, et al ‘Intellectual Property Protection in Africa’.

<sup>160</sup> Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 456 and 472.

favoured principle and national treatment principles under TRIPS negate any legality of a conscientiously weak IP system.<sup>161</sup>

Ginarte and Park observe that, in isolation of an enabling micro and macro-economic architecture, IP protection solely cannot create the conducive environment necessary for innovation and production to thrive. This observation is against their study's finding that apt protection of IPRs necessarily co-hears with presence of a critical size of the research sector. Maskus correctly equally cautions from an economist's perspective, that stronger IPR protection in isolation will not improve prospects of economic growth and development.<sup>162</sup> He rightly argues that there is need to activate an array of other influences including development of robust macro and micro economic policies on taxation, support for literary and technological education, openness to international trade and investment of the one part and embedding IP systems within coherent socio-economic policies and transparent regulation of the other.

Dent<sup>163</sup> highlights the scepticism on utility of a rigorous enforcement of IPRs, including unyielding anti-counterfeit regimes, in developing economies. Indeed, some scholars have sought to advance an epistemological thought, to the effect that it is imprudent for developing economies to adopt these anti-counterfeiting regimes especially on account of their effect of the realization of the right to health,<sup>164</sup> which in Kenya is constitutionally enshrined.<sup>165</sup>

To address these concerns, first, regard must be had to their consistent concurrence that in isolation of other facilitators such as responsive taxation regimes, other enablers of production and a functioning rule of law; IPR protection would certainly have little to no impact in incentivising innovation and investment in the pharma-industry. Further, the concerns against IPR protection, are mitigated by the availability of TRIPS flexibilities to member states in their national interest. So much so, that it is not a debate on whether or not to have IPR protection but how to make use of the flexibilities and have a sui generis regime responsive to Kenya.

These flexibilities are available to cure the challenge of access, and in fact the UN urges that these flexibilities are available to incentivize investment (including foreign investment) in local

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<sup>161</sup>Sihanya B, Intellectual Property and Innovation Law in Kenya and Africa, 464.

<sup>162</sup>Maskus K, Intellectual Property Challenges for Developing Countries.

<sup>163</sup> Dent AS, Intellectual Property, Piracy, and Counterfeiting.

<sup>164</sup> Von Braun J and Munyi P, New Enforcement Mechanisms Challenge the Legality of Generics in the Name of Public Health: The Emergence of Anti- Counterfeiting Legislation in East Africa *African Journal of International and Comparative Law*, Aug Vol, 2010, Vol 18, No 2, 238-253.

<sup>165</sup> Article 43, Constitution of Kenya.

pharmaceutical production. A taskforce by the Kenyan Ministry of Health<sup>166</sup>, established to address parallel importation, counterfeits and illegal trade in pharmaceutical products, similarly conducted a study and established that indeed TRIPS - which enjoins member states to protect IPRs within their jurisdictions – has entrenched flexibilities which create exceptions and limitations on an IPR owners exclusive rights; and these exceptions and limitations properly used can adequately redress the challenge apprehended on a regime for the creation, and apt protection of IPRs over pharmaceutical products.

Ill-advisedly Kenya's approach especially in a far as scoping is concerned currently appears to have focused on adopting as broad as scope as possible; this has a direct impact on the capacity technical and administrative to enforce but also more importantly unnecessarily encumber what would otherwise be licit pharma-products. There is also a seemingly deliberate omission on the challenges faced by prevalence and proliferation of technology and e-commerce. The premise of availing protection for IPRs especially within the pharma industry being clear, from the preceding discussions not least because of the negative impact absent protection would cause.

But additionally, and particularly important for Kenya a report by the British Council in Kenya established<sup>167</sup> that as at 2017, 22% of Kenyan youth were unemployed, with an average of a staggering 500,000 to 800,000 entering the job market annually. This is against a youth population of approximately 10 million, averaging 20% of her total population. To mitigate these alarming statistics the country ought to conscientiously avail opportunities for paying employment, or other ways of gaining personal economic independence. The pharma industry is one key sector that could be leveraged with appropriate interventions, and this paper argues, including apt enforcement of intellectual property rights within the pharma-industry.

A projected direct consequence of the much publicized “Jubilee big 4 Agenda” championed as the pillars of president Kenyatta's legacy is the creation of 1.3 Million jobs in the manufacturing sector.<sup>168</sup> These employment opportunities can be achieved through both gainful employment and self-employment. Mwangi, the Executive Secretary of the Kenya Association of Pharmaceutical Importers (KAPI) – a Kenyan lobby group by pharmaceutical companies who research, develop, manufacture and bring to market novel (new) drugs - notes that Kenya has the largest pharmaceutical market in the EAC, estimated to be worth 75 billion Kenya Shillings in 2014. But even more importantly she notes that the, “world's top 10

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<sup>166</sup> Pharmacy and Poisons Board, *Task-Force Report on Parallel Importation, Counterfeits and Illegal Trade in Pharmaceuticals*, Ministry of Health <http://apps.who.int/medicinedocs/documents/s21359en/s21359en.pdf>

<sup>167</sup> British Council, *Youth Employment in Kenya*, October, 2017  
[https://www.britishcouncil.co.ke/sites/default/files/ng\\_youth\\_employment\\_in\\_kenya.pdf](https://www.britishcouncil.co.ke/sites/default/files/ng_youth_employment_in_kenya.pdf).

<sup>168</sup> Lang'at P, 'How Uhuru hopes to achieve Big Four Agenda,' *Daily Nation*, 24 January 2018, 4.

pharmaceutical companies (with a combined revenue of about \$330 billion in 2017) through representations, local affiliates and distributors, buttresses the country's attractiveness for investment."<sup>169</sup> With the correct regime supporting the pharma sector these figures can be bettered, for Kenya's benefit.

### 3.3 Core challenges reposed in Kenya's current anti-counterfeit legal regime

This study had under chapter two above, critiqued the primary legal regime currently actuated in Kenya to combat counterfeit in pharma: having discussed the causal effect of counterfeits on the growth of country's pharma industry; this chapter concludes with a discussion highlighting three (3) core challenges identified as most impacting Kenya's anti-counterfeit regime and consequently limiting the growth of the country's pharma industry. The World Health Organization (WHO) in urging for enactment for responsive legal regimes, further cautions through the guidelines for the Development of Measures to Combat Counterfeit drugs, under the Department of Essential Drugs and other Medicines, that the counterfeiting problem is "more pronounced in countries where the manufacture, importation, distribution, supply, and sale of drugs are less regulated and the enforcement is weak."<sup>170</sup>

#### 3.3.1 Conceptualisation and scoping of what is counterfeit under Kenyan Law

The *First* challenge discerned in this study, is the concern accruing from the definition of what is counterfeit, and the consequent implausible scope for effective enforcement that this broadened definition creates. The Anti-Counterfeit Act, 2008 defines counterfeit as:

"counterfeiting, means taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya or outside Kenya in respect of protected goods..." (emphasis added)<sup>171</sup>

This definition creates the broad scope of what is counterfeited to include IPRs registered in Kenya's and those that have not. Traditionally, IPR owners enjoy exclusive rights over their IPRs within countries where such right has been recognized in law. Indeed, Kenya has enacted various IP statutes recognizing various IPRs including the Copyright Act<sup>172</sup> recognizing

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<sup>169</sup>Mwangi W, "Big Pharma's healthy contribution", 18.

<sup>170</sup>WHO, Department of Essential Drugs and other Medicines, 'Guidelines for the Development of Measures to Combat Counterfeit Drugs' (WHO/ EDM/ QSM/ 99.1) [https://apps.who.int/iris/bitstream/handle/10665/65892/WHO\\_EDM\\_QSM\\_99.1.pdf;jsessionid=A3D372202AF5B9386E9D9EBCBF53ABC1?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/65892/WHO_EDM_QSM_99.1.pdf;jsessionid=A3D372202AF5B9386E9D9EBCBF53ABC1?sequence=1) accessed 27 April 2019

<sup>171</sup> Section 2, Anti-Counterfeit Act, 2008 (as amended in 2018 by Statute Law (Misc Amendments) Act no 18 of 2018

<sup>172</sup>The Copyright Act, 2001 Laws of Kenya.

copyrights, and for registrable rights the Trademarks Act<sup>173</sup>, recognizing on trademarks, the Seeds and Plant Varieties Act<sup>174</sup> recognizing Plant varieties and the Industrial Property Act<sup>175</sup>, recognizing patents and petty patents. The Anti-Counterfeit Act is neither a recognition nor registration statute, this is vested elsewhere. It is solely meant to, ‘prohibit trade in counterfeit goods, to establish the Anti-Counterfeit Agency, and for connected purposes.’<sup>176</sup> However under the 2018 amendments the law allows the ACA to establish a *customs recordal for trademarks* – in addition to the registration of trademarks under the Trademarks Act.

Seemingly however, the definition accords the ACA authority to enforce that which the establishing recognition and registration statutes do not permit: ofcourse minded of any reciprocity agreements that would extend comity. This proposition violates a fundamental principle on territoriality of IPRs and the enforceability of an IPR in a jurisdiction where such right is recognized. This definition was previously declared unconstitutional and struck out by the Kenyan High Court, but the National Assembly seemingly ignored the substantive questions posed by the Court with regard to the effect on the right to health actualized by access to generics, in its judgment in Patricia Asero Ochieng, Maurine Atieno and Joseph Munyi v The Republic, 2012.<sup>177</sup> The UNCTAD had noted<sup>178</sup> that the 2008 Act, could be easily misunderstood and misinterpreted by the Court, resulting in the application of criminal sanctions to cases of potential patent infringement that occurs in the context of generic activities.

It is noteworthy that the Act sets out a particular scope in reference to medicine or pharmaceutical products in further defining the scope of counterfeits thus,

“...in relation to medicine, (counterfeiting means) 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.”

The focus in this definition quite patently does not seek to address substandard medicines, in so far as the medicines may have deficiencies in quality, efficacy or safety. Which deficiency raises significant public health questions, perhaps rightly so as this is not an IP question, but looking at the dire consequences the superficial reference to serious concerns that would

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<sup>173</sup>The Trademarks Act, CAP 506 Laws of Kenya.

<sup>174</sup>The Seeds and Plant Varieties Act, 326 Laws of Kenya.

<sup>175</sup>The Industrial Property Act, 2001 Laws of Kenya.

<sup>176</sup>Preamble, the Anti-Counterfeit Act, 2008 Laws of Kenya.

<sup>177</sup>PAO and 2 Others V R (2012) eKLR

<sup>178</sup>The UNCTAD-UNIDO, ‘TRIPS Flexibilities and Anti-Counterfeit Legislation in Kenya and the EAC: Implications for Generic Producers,’ 2016.

require substantive consideration and redress appear unaddressed. However, product quality is not the focus of this study.

A different concern on scoping is the extension of anti-counterfeiting to all IPRs, and not just limited to trademarks and/or copyrights and related rights. Such that under Kenyan Law, all IPRs including patents, plant varieties are all subject of anti-counterfeiting law. The practicality of enforcing some of this IPRs, which would often require some considerable effort in time and technical competence in examining negates the effort of the enforcement.

This peculiar change under Kenya's Anti-counterfeit regime is a significant departure from the standards under TRIPs,<sup>179</sup> which anticipates application of anti-counterfeit laws to trademarks and copyright and related. Importantly TRIPs only prescribes minimums and Kenya is at liberty to enhance the level of protection; but where such "enhancements" have a deleterious on not just international trade but the very growth of industry in the country, then such supposed enhancements ought to be voided.

Most certainly, the extended scoping of counterfeits under Kenyan law goes contrary to the establishment of an effective enforcement regime, unnecessarily exposing the work at the ACA to challenge for want of legal plausibility and certainty. Anyangu-Amu (in writing about the 2008 Act, which the country has reverted to vide 2018 amendments to the law) notes that Kenya's broad conceptualisation creates confusion between counterfeits and generics. This broad scoping disregards the premise of limiting counterfeiting action to Trademark counterfeiting and copyright piracy, both of which are easily identifiable visually.<sup>180</sup>

Additionally, 'unlike trademarks or copyright patent infringement cannot be established without expert investigations including determination whether there is 'equivalence' or not.'<sup>181</sup> Countries with high level of patent protection omit patent rights from scope of counterfeits, importantly because with such a broadened scope we'll have enforcement officials trying to figure out whether drugs are counterfeit or not increasing risks of seizure and lawful products being labelled fake, as well as delays at entry points on verifications and also unnecessarily attracting costs to disprove 'fakeness' ultimately increasing per-unit costs for the affordable medicine.<sup>182</sup> The expertise to detect such lies with the Pharmacy and Poisons Board (PPB)

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<sup>179</sup> Footnote 14, Article 61, TRIPs Agreement.

<sup>180</sup> Kaindo P, Overlapping IP Rights pose tough challenges, Business Daily, 28 November, 2018 [www.businessdaily.com/analysis/ideas/overlapping\\_IP\\_rights\\_pose\\_tough\\_challenge/4259414\\_4873170\\_14g8yz/index.html](http://www.businessdaily.com/analysis/ideas/overlapping_IP_rights_pose_tough_challenge/4259414_4873170_14g8yz/index.html)

<sup>181</sup> ICISP-UNCTAD Capacity Building Project on IPRs and Sustainable Development.

<sup>182</sup> Anyangu-Amu S, Kenya Anti-counterfeit Law Violates Right to Health.

which in law already is required to authenticate medicinal potency and safety of pharmaceutical products imported into Kenya.

### 3.3.2 *Inadequate capacity of the enforcement agencies*

*Secondly*, the Kenya Association of Manufacturers has decried the limited number of enforcement officers at the ACA, available to undertake the wide ranging detection, investigations, seizures and possible subsequent prosecution.<sup>183</sup> Sihanya highlights that the ACA though critical in fight against counterfeits, is characterised by an insufficient and untrained human resource unable to manage the volume and complexity, evincing general and technical ignorance.<sup>184</sup> The ACA being a state agency tasked with the mandate to enforce against counterfeits having such limited numbers, can obviously do very little impactful work: this is because the concerned officers would be stretched too thin to meaningfully discharge their mandate. The Act to cure this challenge provides that the ACA works in collaboration<sup>185</sup> with the designated anti-counterfeit inspectors who include member of the ACA Board, National Police Service officers, 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 (Cap. 496), the Weights and Measures Act (Cap. 513), the Copyright Act (No. 12 of 2001), the Food, Drugs and Chemical Substances Act (Cap. 254), the Pharmacy and Poisons Act (Cap. 244) and the Pest Control Products Act (Cap. 346).<sup>186</sup>

This challenge is even more real, as read with the broad scope of what the ACA is currently legally empowered to enforce. The current scope of what the ACA can enforce including IPRs such as Patents, protected Plant Varieties, Utility Models registered in Kenya and elsewhere; the technical competence required to effectively enforce these more intricate IPRs certainly undermines the apt enforcement of IPRs. This challenge appears to, almost in equal measure tease counterfeiters and mock IPR owners as it grants a virtually unenforceable right and at best exposes this power to possible abuse. Due regard is required in ensuring that the enforcement agencies are adequately capacitated to enable it effectively discharge its mandate. Sihanya notes that efficiency in the anti-counterfeiting legal system extends to capacity challenge in monitoring border measures and also limited expertise in practitioners, administrators and judicial officers.<sup>187</sup> He however highlights that having contrasted law

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<sup>183</sup> <http://kam.co.ke/policy-advocacy/counterfeit-goods-illicit-trade/>.

<sup>184</sup> Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 619 and 620.

<sup>185</sup> Rutenberg, I, Ouma M and Munyi P, 'Kenya': In *International Encyclopedia of Laws: Intellectual Property Law* (ed) Hendrik Vanhaes Alphen aan den Rijn: (2019) Kluwer Law International.

<sup>186</sup> Section 22(3), Anti-counterfeit Act, 2008.

<sup>187</sup> Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 444.

enforcement in 1990 and 2005, a stark similarity on inability to distinguish fake from genuine is a major concern. He also highlights ‘rent-seeking’ corruption and complicity as part of influencers for inefficiency amongst law enforcement – which can be cured and/or mitigated through adequate incentives such as better terms and conditions of service.<sup>188</sup>

The government has itself acknowledged this limitation and in seeking to curb counterfeiting, established a Multi-Agency Task Force under the Executive Office of the President led by Wanyama Mutsiambo, the Deputy Head of Public Service. This task force includes representation from the Ministry of Industry, Trade and Cooperatives, State Department for Trade; the Kenya Revenue Authority, the Kenya Copyright Board, Pest-Control Products Board, the Anti-counterfeit authority, the Attorney General’s Office, the Kenya Bureau of Standards, and the Pharmacy and Poisons Board. The establishment of the taskforce was in recognition of the need to collate and leverage the efforts of these various agencies and their technical expertise. It is however important to entrench such an initiative in law to define their mandate and power. But even with this enhanced capacity, technology makes it even more difficult for the already technically challenged enforcement officials, to distinguish genuine from counterfeit this is because the counterfeits often look glossier and more genuine than the genuine product.<sup>189</sup>

Counterfeiting is increasingly emerging as predominantly cross-jurisdictional. However, there is an absence of competent regional and sub-regional judicial tribunals to deal with such cross-jurisdictional issues where they emerge. These necessarily means that the enforcement agencies would not have the benefit of such fora to adjudicate over such concerns whenever they arise. A solution might be to effect amendments on the jurisdiction of the ARIPO Tribunal (and OAPI High Commission for Appeals) to confer jurisdiction on cross-jurisdiction counterfeiting. Alternatively, bilateral treaty amongst different countries may allow and confer jurisdiction as appropriate.

Still on the challenge in capacity, the ACA Executive Director now has authority to ostensibly record confessions and punish suspected counterfeiters. The Act despite creating this power does not make provision for the procedure to be adopted on the recordal of these confessions (if at all), and an attendant appellate mechanism. This is in violation of Article 47, Constitution of Kenya, and the Fair Administrative Actions Act, both of which impose a very high standard for fair administrative action. This is certainly an encumbrance on ACA’s capacity. Susan Sell cautions that conferring such broad powers, on enforcement agencies without training on

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<sup>188</sup> Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 488.

<sup>189</sup> Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 460.

handling or resolving complex legal disputes on alleged infringement cases will actually cause collapse of ‘suspects’ who after all end up being innocent.<sup>190</sup>

### 3.3.3 *Proliferation of counterfeit pharma in the online market place*

*Lastly*, the effective enforcement against the illicit counterfeit trade faces an all too familiar challenge accruing from the emergence of technology and increased penetration and proliferation of internet and e-commerce. Kenya continues to witness a steady exponential growth of internet access, across the length and breadth of the country. The Communications Authority of Kenya (CA), in its Third Quarter Sector Statistics Report for the Financial Year 2017/2018 notes that, “(Kenya’s) total data/Internet subscriptions grew (from the last review) by 8.2 percent, to record 36.1 million subscriptions (up) from 33.3 million recorded during the second quarter of the same financial year.”<sup>191</sup> The report further highlights the total internet subscriptions as standing at 36.1 million subscriptions as at March 2018, growing from the previous 25.7 million in March 2017. The CA attributes the growth in internet subscription to the proliferation of smart phones used to access social media sites<sup>192</sup> and possibly e-commerce platforms.

As this author has urged separately in a blogpost published by CIPIT, “the growth in internet access and digital communication technologies, has expanded the vulnerability to increased infringement of IPRs through pirated-copyright works<sup>193</sup> and counterfeited products. The nature of internet and digital communication technologies therefore not only increases by the volumes, the number of potential counterfeiters, but it also heightens the exposure to possible infringement over the internet. The ease of modification and replication, coupled by access, reach; evinces the vulnerability and brings into focus the legal environment available for asserting and protecting IPRs in this space. Consequently, from an enforcement perspective, the IPR owners are more vulnerable in a social-media internet era.”<sup>194</sup> Due to the relative anonymity in e-commerce legit traders and counterfeiters are becoming synonymous, making it difficult to tell the two apart. Counterfeiters are able to anonymously market and sell their illicit wares online and delete any evidence immediately payment is received.<sup>195</sup>

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<sup>190</sup>Sell S, *The Global IP Upward Ratchet, Anti-counterfeiting and Piracy Enforcement Efforts*, 19.

<sup>191</sup> Communications Authority of Kenya, *Third Quarter Sector Statistics Report for The Financial Year 2017/2018*, 15

<sup>192</sup> Communications Authority of Kenya, *Third Quarter Sector Statistics Report for The Financial Year 2017/2018*

<sup>193</sup> L. Bently & B. Sherman, *Intellectual Property Law* (4th ed), Oxford 2014, 303

<sup>194</sup>Lusi W, *Fakes and pirates online: Is it an unregulated space in Kenya*, 7 May 2019, on <https://blog.cipit.org/2019/05/07/fakes-and-pirates-online-is-it-an-unregulated-space-in-kenya/>

<sup>195</sup> Sihanya B, *Intellectual Property and Innovation Law in Kenya and Africa*, 461.

A number of small and medium sized pharma business have taken advantage of the sizeable online marketplace.<sup>196</sup> Not only is there an upsurge in pharma-boutique e-commerce platforms other than the start-ups, a number of established pharmacies have also established online stores,<sup>197</sup> this in addition to the ‘general’ e-commerce platforms that avail pharma products (and potentially counterfeit pharma products) as part of their product offerings.<sup>198</sup>

This author further urged in the blogpost that, “the online market space enhances ease of access but with little opportunity for verification of the authenticity of the products being traded in the online market place. The buyers would favor the convenience especially for the sale of goods, but most aren’t allowed an opportunity to ascertain the ‘authenticity’ or otherwise of the products being traded in the platforms. The bigger enterprises<sup>199</sup> have equally sought to align their marketing strategies and distribution to leverage on the online sphere.”<sup>200</sup>

The Kenyan law does not appear responsive to the emergent challenges from the new technologies and the e-commerce market. As urged in my published blogpost, “the current legal regime is not adequately framed to address piracy and counterfeiting in the online market place, and much like established e-commerce platforms the options remain limited to self-help strategies adopted including authentication services, and, accreditation and registration of merchants.”<sup>201</sup>

Earlier this year, the Court of justice of the European Union declined an invitation to hold online marketplaces directly liable for trade mark infringement on their platforms.<sup>202</sup> The court in acknowledging that online marketplaces are frequently used for the sale of counterfeit goods however, held that these platforms remain ‘intermediaries’ in the sense that they do not participate in the sale and purchase transaction.

Gommers, C. and Eva De Pauw, in their article<sup>203</sup> highlight the inefficacies of the ‘traditional enforcement’ measures to curb the sale of counterfeits (generally) in the online marketplace. They address their study on the role played by online marketplace operators in the illicit

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<sup>196</sup> [www.mydawa.com](http://www.mydawa.com); <https://pharmacydirectkenya.com> and <http://www.pharmashop.co>

<sup>197</sup> <https://www.malibupharmacy.co.ke>, and <http://www.kampharmacy.com>

<sup>198</sup> <https://www.jumia.co.ke/health-beauty/?q=medicine>

<sup>199</sup> <https://www.economist.com/business/2018/07/05/amazon-takes-a-big-step-into-online-pharma>

<sup>200</sup> <https://blog.cipit.org/2019/05/07/fakes-and-pirates-online-is-it-an-unregulated-space-in-kenya/>

<sup>201</sup> <https://blog.cipit.org/2019/05/07/fakes-and-pirates-online-is-it-an-unregulated-space-in-kenya/>

<sup>202</sup> Case C-567/18 Coty Germany GmbH/Amazon Services Europe Sàrl and Others, ECLI:EU:C:2020:267, 2 April 2020.

<sup>203</sup> Gommers C. and Pauw E.D. ‘Liability for trade mark infringement of online marketplaces in Europe: are they ‘caught in the middle’?’

See <https://jiplp.blogspot.com>

counterfeit trade. They urge that in applying the principles in the, *E-Commerce Directive*<sup>204</sup> and the *IP Enforcement Directive*:<sup>205</sup> ultimately holding the operators liable (in as far as they derive a discernible economic benefit from the online trade) for infringing products sold through their platforms, will ultimately enhance effective curbing of counterfeit trade. Kenya's pharma industry can equally benefit through establishing, "an equitable balance between the interests of online marketplace operators and the interests of trade mark owners (could be) found by imposing higher monitoring duties on online marketplace operators assuming an 'active' role."<sup>206</sup> The proposal by Gommers and Pauw is an extrapolation of the principles used to hold Internet Service Providers (ISPs) liable for copyright infringement, should they run afoul the exemption under the 'safe harbor principles.' The Kenya Copyright Act (as amended in 2019) makes provision for ISP liability but only as far as copyright is concerned, a contemporaneous amendment in the Kenya Information and Communication Act might be necessary to incorporate the proposal: absent which no *sui generis* law effectively addresses the peculiarities brought about by infringement in the online marketplace.

Ultimately however, in concurring with Amor Toumi, this study notes that fundamentally, IP solely cannot curb counterfeit pharma. Counterfeit medicine is first and foremost a problem of public health, and must be considered as such. So that much as the concerns on Intellectual property infringement subsist, but they are secondary to the problems of public health. This exposition is not to suggest that IPR enforcement needs to be regarded any less, simply that the enforcement measures mustn't negate public health concerns. From the foregoing, the author agrees with Amor Toumi that enforcement of pharma intellectual property rights cannot - *done in isolation* - apprehend the magnitude and the specificities of the issues raised by counterfeit pharma which has become a global health scourge causing the death of millions of people<sup>207</sup> and thus the war on pharma counterfeiting requires a wholesome approach.

### 3.4 International Best Practise: A Comparative Study

The comparative study discourse herein, focuses on the measures adopted in the Republic of South Africa and in the United states of America, as against the three (3) core challenges highlighted above as substantively impacting the enforcement against counterfeit pharma in

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<sup>204</sup> DIRECTIVE 2000/31/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce):

see <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000L0031&from=EN>

<sup>205</sup> DIRECTIVE 2004/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the enforcement of intellectual property rights.

See: [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004L0048R\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004L0048R(01)&from=EN)

<sup>206</sup> See note 150

<sup>207</sup> <https://www.iracm.com/en/thematic-observatory/intellectual-property/>

Kenya i.e. scoping of counterfeits, the capacity and lastly the initiatives adopted to curb counterfeiting in the online marketplace.

This study settled on these two jurisdictions as they have fairly robust pharmaceutical industries, but also a fairly successful enforcement regime. Invariably there are tacit nuances in these countries that may occasion a difference in the level of successes even with the adoption of their measures within the scope of these study's focus: this paper however exposes the inefficacies of the Kenyan regime as a result of the differences in the approach between these countries and Kenya on addressing these challenges highlighting lessons to be learnt by Kenya.

### ***3.4.1 Analysis of the anti-counterfeiting regime in the Republic South Africa***

The Republic of South Africa (RSA) admittedly has a fairly advanced and large economy, its pharmaceutical sector is valued at an impressive average of between R42.6bn and R45bn as at 2016. Current estimates put the valuation of the sector at about R50bn as at 2019 manufacturers' exit price and R68bn using retail sales.<sup>208</sup> It is reported that the Department of Health and the Medical Controls Council (the RSA state organ mandated to license pharmaceutical companies) had licensed about 276 companies as at 2016.<sup>209</sup> Notoriously the RSA, has had a challenge of availing adequate medical care to respond to high HIV infections; such that how it has availed access to right to health, with a correspondingly robust pharmaceutical industry under a sui generis anti-counterfeiting law will offer useful comparison for Kenya against the three (3) core challenges which is focus in this study.

The anti-counterfeiting legal regime in the RSA is anchored on the Counterfeit Goods Act, 1997. The Kenyan Anti-Counterfeit Act substantively mirrors (and was indeed modelled) on the RSA's Counterfeit Goods Act, 1997. This RSA legislation was subsequently amended in 2001 by the Counterfeit Goods Amendment Act, 2001.

On the first challenge on *scoping*, the Counterfeit Goods Act, 1997 (the RSA's original legislation) defined counterfeiting, and consequently the scope of application of anti-

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<sup>208</sup>The Pharmaceutical industry in South Africa, 2019, Research and Markets (April, 2019) [https://www.researchandmarkets.com/reports/4761608/the-pharmaceutical-industry-in-south-africa-2019?utm\\_source=CI&utm\\_medium=PressRelease&utm\\_code=27wgp9&utm\\_campaign=1263147+-+South+Africa+Pharmaceutical+Industry+Report+2019&utm\\_exec=chdo54prd](https://www.researchandmarkets.com/reports/4761608/the-pharmaceutical-industry-in-south-africa-2019?utm_source=CI&utm_medium=PressRelease&utm_code=27wgp9&utm_campaign=1263147+-+South+Africa+Pharmaceutical+Industry+Report+2019&utm_exec=chdo54prd)

<sup>209</sup><https://www.marketwatch.com/press-release/south-african-pharmaceutical-industry-2017-2018-with-88-company-profiles-including-pfizer-aspen-and-roche---researchandmarketscom-2018-07-19>

counterfeiting measures to only intellectual property rights registered in the RSA.<sup>210</sup> Further however, the Act extends clarity on the import of the scope of what is capable of being counterfeit(ed) and thus subject to the mandate and jurisdiction of the Act as a protected good for which intellectual property right obtains; by defining intellectual property rights (for purposes of the Act) within a limited scope to only Trademarks and Copyrights.<sup>211</sup>

Such definition adopted by the RSA excludes all other IPRs including the patents, Plant Varieties *inter alia* from within the scope of the anti-counterfeiting law. The consequent effect is to alleviate the challenge that would be otherwise posed by the technical nature of some of these IPRs, necessarily limiting the anti-counterfeit enforcers' ability to effectively discharge their mandate.

In terms of scoping therefore the RSA anti-counterfeiting regime aptly limits the scope to the IPRs registered and/or recognized in RSA. Secondly it limits its scope to only trademarks and counterfeits. However, no particular or specific mention/definition is made of medicine or pharma products in the Counterfeit Goods Act. The Act opts to address itself solely to the IPR.

Secondly this study has highlighted one of the core challenges posed on efficacy of anti-counterfeit enforcement in Kenya as being the capacity of the enforcement officials. The RSA's Counterfeit Goods Act establishes the offices of inspectors, where any apprehensive owner of an IPR (being either copyright or trademark owner) may lodge a complaint with any inspector.

Of significance to this study however, is that the RSA Act allows under Section 1(x) as read with Section 15(9) thereof for the appointment of other officers, and/or confers additional officers with the authority and mandate of an inspector under the Act. These include any police officers under the Criminal Procedure Act<sup>212</sup> of the rank of sergeant and above, and the Commissioner of customs as well as officers of the South African Revenue Service's Customs and Excise Department. This significantly helps complement the human resource numbers available to undertake enforcement of IPRs.

Further the Counterfeit Goods Act, 1997 strictly provides that an inspector may only enter, inspect seize and or otherwise impound/detain or interfere with suspected counterfeit goods on the strength of a warrant. This notwithstanding if any action by an inspector is not subsequently confirmed by a court within ten (10) days thereof, then such act stands voided and any seized goods returned to the 'suspect'. Indeed, this ensures effective judicial oversight over the

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<sup>210</sup> Section 1(1)(iv), Counterfeit Goods Act, 1997 (of South Africa).

<sup>211</sup> Section 1(1)(xi), Counterfeit Goods Act, 1997 (of South Africa).

<sup>212</sup> Criminal Procedure Act, 1977 (of South Africa)

discharge of the broad (almost draconian) powers vested on the inspectors to enter private premises and seize without prior notice or warning.

Lastly, on the challenge of online infringement, the RSA Counterfeit Goods Act, proscribes putting up for for sale, hiring out, barter, exchange; or, exposing for sale, for barter or for exchange; exhibition in public for purposes of trade; distribution for purposes of trade, or for any other purposes to such an extent that the owner of an IPR in respect of any particular protected goods suffers prejudice; imports into, through or export from; or in any other manner dispose of in the course of trade.<sup>213</sup>

This provision effectively avails itself to facilitating assumption of jurisdiction over infringement in the online market place. The online market place avails itself to offer for sale and/or distribute (possibly) counterfeit goods, and the very nature of the online market place (afore-discussed) challenges the traditional mechanisms hitherto established for purposes of combating illicit trade in counterfeit pharma. To the extent that the RSA law proscribes the key attributes of the illicit trade online then it seeks to address counterfeit within the e-commerce sphere. But certainly, a more direct address of the concern is preferable.

### ***3.4.2 Analysis of the Anti-Counterfeit Regime in the United States of America***

As a preliminary the US Department of Commerce notes that pricing of Pharma products is designed to ensure that the investment towards past and future Research and Development Costs are recouped. It further notes that the industry is heavily dependent on development of new molecules to replace the revenue streams of older drugs that are nearing the expiration of their patent terms.<sup>214</sup> Quite clearly guaranteeing the ability to secure return on investment made in the R&D would necessarily mitigate the overall cost of the drugs. This USDC/ITA report urges for adoption of measures that would enhance R&D in the sector but also not unduly curb growth of ‘new medicine’ – generics. So how exactly does the US market address this concern?

The US anti-counterfeiting regime is enforced under the Trademark Counterfeiting Act, 1984<sup>215</sup> which equally relies on the preceding registration of a trademark as such under the Lanham Act.<sup>216</sup> In an article by Brian J. Kearney, he observes that the United States of America (US) anti-counterfeit law has a long troubled past with the US Congress’s hitherto unsuccessful

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<sup>213</sup>Section 2(1)(a),(c),(d),(e)&(f), Counterfeit Goods Act, (of South Africa).

<sup>214</sup>US Department of Commerce, International Trade Association, 2016 Top Markets Report Pharmaceuticals, [https://www.trade.gov/topmarkets/pdf/Pharmaceuticals\\_Top\\_Markets\\_Reports.pdf](https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_Top_Markets_Reports.pdf)

<sup>215</sup> US Title Code 18, Section 2320 Trafficking in Counterfeit Goods and Service (of the United States of America)

<sup>216</sup> US Title Code 15, Section 1051 Trademarks Act (of the United States of America).

attempts to impose criminal sanctions for commercial violation of trademarks,<sup>217</sup> with the US Supreme Court striking out previous attempts for want of constitutional authority, ultimately leading to the enactment of the Trademark Counterfeiting Act in 1994. This enactment had been constrained by three key factors, *first* deficiencies in the Lanham Act to deter through sanctions - commercial counterfeiters; increase in demand for counterfeits as a result of growth in mass advertising (consumer accomplices discussed above); and, advances in technology that made it easier to counterfeit.<sup>218</sup> This article also importantly highlights these contestations made with regard to the definition and/or scoping of counterfeiting under the Acts, enforcement capacity and online marketplace infringement; as challenges currently afflicting the efficacy of Kenya's anti-counterfeit regime.

In seeking to adequately deter counterfeiting, the Trademark Counterfeiting Act created 'tripled-graduated' fines of not more than USD 2 Million or USD 5 Million for first time offenders (for individuals and corporates respectively) and not more than USD 5 Million or USD 15 for second and subsequent offender: and/or longer custodial sentences of not more than 10 or 20 years for first time and repeat offenders respectively.<sup>219</sup> This is addressed in the Kenyan law. However, for counterfeit pharma, the Act created higher fines of not more than USD 5 Million or USD 15 Million for first time offenders (for individuals and corporates respectively) and not more than USD 15 Million or USD 35 for second and subsequent offender: and/or longer custodial sentences of not more than 20 or 30 years for first time and repeat offenders respectively.<sup>220</sup> So that distinct from the approach in RSA there is special consideration for counterfeit-pharma in the primary anti-counterfeiting regime. The Trademark Counterfeiting Act also capacitated enforcement officers through introduction of (ex parte) seizure raids<sup>221</sup> including allowing for forfeiture, destruction and restitution<sup>222</sup> as an additional measure to effectively deter counterfeiters.

The Trademark Counterfeiting Act, particularly defines the *scope* of counterfeit as seemingly limited to trademarks, and further only those registered in the US under the Lanham Act. This *scoping* approach is similar to that adopted by the RSA. Particularly para a(4) of the Lanham Act, the US law proscribes unauthorized use of marks and/or counterfeit marks on drugs. It

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<sup>217</sup> Kearney JB, The Trademark Counterfeiting Act of 1984: a Sensible Legislative Response to the Ills of Commercial Counterfeiting, 1986, *Fordham Urban Law Journal*, Fordham University School of Law Vol 14(1).

<sup>218</sup> Kearney JB, The Trademark Counterfeiting Act of 1984, 132.

<sup>219</sup> (b)1(A)&(B), US Title Code 18, Section 2320 Trafficking in Counterfeit Goods and Service (of the United States of America).

<sup>220</sup> (b)3(A)&(B), US Title Code 18, Section 2320 Trafficking in Counterfeit Goods and Service (of the United States of America).

<sup>221</sup> <https://www.lexology.com/library/detail.aspx?g=3495d584-f988-45ff-8add-7d83bcab50d2>

<sup>222</sup>(c), US Title Code 18, Section 2320 Trafficking in Counterfeit Goods and Service (of the United States of America)

defines a drug against which an anti-counterfeit action may be brought in the US as, “a drug, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). (g)Nothing in this section shall entitle the United States to bring a criminal cause of action under this section for the repackaging of genuine goods or services not intended to deceive or confuse.”<sup>223</sup> In further *scoping*, the US regime creates a prerequisite element of *mens rea* (viz presence intent to deceive or confuse) by requiring establishment of ‘knowingly and intentionally’ in ascribing criminal culpability for the counterfeiting offences.

But additionally at Para H the US Attorney General is required to report on the efforts undertaken by the Department of Justice, in enforcing against criminal infringement of copyright, by inference recognizing the jurisdiction to curb copyright piracy additionally under this Act.<sup>224</sup> So that the regime appears to additionally create an oversight by the legislature on the enforcement measures against counterfeiting and piracy.

Of additional note, the U.S. Congress enacted the Drug Supply Chain Security Act (DSCSA) in 2013, in a bid to address the emerging challenge of online infringement. The Act requires the pharmaceutical industry to adopt, by 2023, an “interoperable system” which will allow easy tracing of prescription drugs as they are distributed in the U.S.<sup>225</sup> The blockchain idea advanced by the DSCSA is simply “a ledger software that creates a tamper-proof, indelible record of transactions. This record of transactions is decentralized, every participant maintains a copy of the ledger and needs to approve any change. Additionally, the system is fully transparent, the list of transactions is visible to everyone.”<sup>226</sup> The DSCSA developed measures that will additionally effectively aid curb the counterfeit menace solved with time. In doing so, the Act proposed;

“..

- (a) Require more information about drug transactions. Starting Jan. 1, 2015, companies in the pharmaceutical supply chain—manufacturers, repackagers, wholesalers, and pharmacies—must share specific data, including the lot number, with all trading partners for each transaction and other changes of ownership. In most cases, the data must document the full purchase and sale history of all drugs in a shipment back to the original manufacturer. This will dissuade illegal activity, such as purchasing counterfeit medicine from an unauthorized foreign supplier, by making the origin and routing of

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<sup>223</sup>(f)(6), US Title Code 18, Section 2320 Trafficking in Counterfeit Goods and Service (of the United States of America).

<sup>224</sup>(h), US Title Code 18, Section 2320 Trafficking in Counterfeit Goods and Service (of the United States of America).

<sup>225</sup>Michelle, ‘Can Blockchain help solve the Problem of Counterfeit Drugs?’ Digital Initiative < <https://rctom.hbs.org/submission/can-blockchain-help-solve-the-problem-of-counterfeit-drugs/>> on 27 April 2019.

<sup>226</sup> Michelle, ‘Can Blockchain help solve the Problem of Counterfeit Drugs?’.

the drugs more transparent. With regular checking of transaction histories, criminals will be deterred from introducing unsafe or compromised medicines of unknown origin into consumer markets.

- (b)** Require unique serial numbers on each package of drug. By the end of 2017, nearly every individual package will carry a unique barcode. This will eventually allow companies along the entire supply chain to verify the authenticity of the drugs they acquire, making it more difficult for criminals to introduce counterfeit drugs into the pharmaceutical supply. Drug packages with fake serial numbers or with packaging that has been inappropriately altered will be easier to identify and remove from circulation.
- (c)** Enhance licensure standards. The law creates a transparent system for pharmaceutical wholesale distributors that establishes minimum standards for licensure in the United States and also requires them to report their licensing status and contact information to the U.S. Food and Drug Administration (FDA). The information will be publicly available through online databases, which will help supply chain stakeholders, including health care providers, avoid purchasing from unlicensed suppliers.
- (d)** Build an interoperable, electronic system. The law requires manufacturers, wholesalers, and pharmacies to use serial numbers and an electronic system by 2023, which captures and shares information in order to trace each package of medicine. The FDA and stakeholders will work together to determine how this system will work and how data will be exchanged. The unique serial numbers will allow any pharmacy or wholesaler to verify the authenticity of a drug package.”



## 4.0 Chapter Four: Conclusions and Recommendations

### 4.1 Findings and Conclusions

First, Article 41, TRIPS Agreement obligates Kenya to ensure that the measures and actions adopted to protect IPRs are effective. TRIPS also provides minimum obligations and Kenya in designing effective actions must be minded not to use the TRIPS as a floor but possibly a ceiling to balance the possible deleterious monopolistic effects of securing IPRs. Indeed, as under TRIPs IP infringement generally is not equated conceptually to counterfeiting. As a key observation, this study has established that indeed the apt protection and enforcement of Intellectual Property Rights, is integral in the advancement of economic development, and more particularly growth of the pharma-industry. Contemporaneously, the study has equally established that apt intellectual property rights enforcement is essential in facilitating the realisation of the right to health. It is therefore critical, that for this synchronised but almost competing interests to be realised, that the responsiveness of the regime established to inter alia enforce intellectual property rights.

The right to health is a global undertaking as expressed in various international treaties principally the Universal Declaration of Human Rights (UDHR),<sup>227</sup> Article 12 of the International Covenant of Socio-Economic Rights (ICESR)<sup>228</sup> and Article 12 of the Convention on All forms of Discrimination against Women. Equally, regionally the Right to Healthcare is also recognised under the African Charter of Human and Peoples Rights<sup>229</sup> under Article 16 thereto. Sustainable Development Goal 3 of the Millennium Development Goals also compels states to ensure the wellbeing for all at all ages. The preceding demonstrates the global significance attaching to the right to health, and in actualizing these globally covenanted standards this study argues apt enforcement of IPRs is peremptory.

Separately against this global premise, it is important to note that no country is immune to counterfeiting in pharmaceutical products.<sup>230</sup> However, the frequency and effects of the said counterfeiting of pharma is higher in countries with comparatively low incomes particularly in Africa and Asia.<sup>231</sup> An inefficacious enforcement for IPRs in the pharma-industry has seen a

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<sup>227</sup>Article 25, Universal Declaration of Human Rights (UDHR).

<sup>228</sup>Article 12, International Covenant of Socio-Economic Rights.

<sup>229</sup>Article 16, The African Charter of Human and Peoples Rights (ACPHR).

<sup>230</sup>Shrivastava SRB, Shrivastava PS, and Ramasamy J, 'Public Health Measures to Fight Counterfeit Medicine Market', 2014, 5(3) *International Journal of Preventive Medicine* 370-371 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4018649/>.

<sup>231</sup>Shrivastava SRB, Shrivastava PS, and Ramasamy J,, 'Public Health Measures to Fight Counterfeit Medicine Market'.

flourishing illicit business of production and sale of counterfeit drugs. As afore-urged, Kenya is one of the countries with an ineffective anti-counterfeiting regime. The challenge from counterfeit-pharma is global and various measures continue to be adopted in an attempt to weed-out counterfeit drugs.

It is against this premises that this study considers available measures for enhancing Kenya's IPR enforcement regime with regard to anti-counterfeiting through considering measures adopted by different stakeholders in the pharma industry, both internationally and regionally, in an effort to curb this pharma-counterfeit.

In enhancing the enforcement regime, Shrivastava, Shrivastava, and Ramasamy propose 7 defined parameters for consideration and adoption by governments in a bid to combat the menace of counterfeit medicine;

“...

- (a) First and foremost, requirement is to have an exact estimate of the nature and extent of the counterfeit drugs problem in the country so that scarcely distributed resources can be utilized to the optimal extent,
- (b) The policy makers should formulate a comprehensive policy to address all the potential threats in the field of counterfeit medicine market,
- (c) Subsequently, strategy should be to actively involve all stakeholders namely health authorities, drug regulatory authorities, wholesalers, retailers, police, customs, judiciary, pharmaceutical industry and patients. Creating awareness among the population regarding generic drugs and the dangers of the illicit medicines with the help of appropriate mass media aids is of paramount importance,
- (d) Designing appropriate laws with the help of legal department and facilitating their strict enforcement; providing legal assistance to the consumers; and employment of strict pharmacovigilance mechanisms,
- (e) Organizing training sessions for the benefit of pharmacists and health care professionals in different aspects of counterfeiting,
- (f) Building of a network to strengthen collaborative activities at local, district, regional, national and international levels; and ensuring continuous monitoring and evaluation of implemented measures,

- (g) Adoption of newer technologies like use of cost-effective electrophoresis devices/more sophisticated devices for warranting quality assurance of drugs.”<sup>232</sup>

In evaluating the efficacy of Kenya’s regime enacted to curb pharma counterfeiting this study, reference is made to the above recommendations, as against the lenses of the three (3) core challenges the focus of this study first, scoping of protection; secondly capacity of the enforcement agency; and lastly, prevalence of counterfeit pharma in the online market place. Being minded to particularize the solutions to Kenya, as ‘localized’ solutions have in many instances proved to be central to any successful effort<sup>233</sup> to curb pharma-counterfeits.

## 4.2 Recommendations

In deed this study has evinced the gravity of the counterfeiting menace globally and particularly in Kenya. It has further particularised this concern within the pharma-industry. Additionally, this study also considered what appears to be effective measures adopted by the United States of America and the Republic of South Africa, as against the regime adopted in Kenya *vis-à-vis* her obligations under TRIPS. However, as discussed in the preceding chapter any strategy adopted may be remiss on account of absence of accurate data on the exact scope and quantum of pharma counterfeiting amounts.<sup>234</sup> In Kenya, one of the biggest challenges has been that pharma-companies do not report infringement of their patents and trademarks in the pharmaceutical industry.<sup>235</sup>

As afore-urged by various epistemological thoughts, without a threshold in research, IP protection would be unsustainable but equally without IP protection research would be unviable. The USDC/ITA significantly highlights that in 2016 the pharma-industry invested a whopping 34 Billion Euros in R&D and that ostensibly, “geographical balance of the pharmaceutical market – and ultimately the R&D base – is likely to shift gradually towards emerging economies.”<sup>236</sup> Having considered the direct benefits of a robust IPR enforcement

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<sup>232</sup>Shrivastava SRB, Shrivastava PS, and Ramasamy J,, ‘Public Health Measures to Fight Counterfeit Medicine Market’.

<sup>233</sup>Muhammad Hamid Zaman, ‘How do we Combat the Problem of Counterfeit Drugs?’ (2015) World EconomicForum <https://www.weforum.org/agenda/2015/08/how-do-we-combat-the-problem-of-counterfeit-drugs/>

<sup>234</sup> <<https://www.ip-watch.org/2017/08/30/better-data-fake-drugs-needed-fight-scourge/>

<sup>235</sup> <<https://www.capitalfm.co.ke/business/2013/08/we-cant-do-much-until-fakes-reported-agency/>> accessed 28 April 2019.

<sup>236</sup>DiMasi AJ, Grabowski HG, Hansen RW, Innovation in the pharmaceutical industry: New estimates of R&D costs, Journal of Health Economics, 47, 2016, 20–33.

regime and incentives for growth; it then behoves Kenya to develop her IP enforcement regime and lay premise for exponential growth of its pharmaceutical industry.

This study's *raison d'être* is leveraging of adequate protection of IPRs within the pharmaceutical industry as a means of facilitating achievement of the development including under the Big Four Agenda: Hence the isolation of the three (3) core challenges of Kenya's anti-counterfeiting enforcement for critique within the context of the utility of (criminal) IPR enforcement. The Principal Secretary in the Ministry of Trade noted during the launch of the IP enforcement working group, that the protection and enforcement of IPRs was indeed a key incentive towards the promotion of the manufacturing sector.<sup>237</sup>

Further, with the emergence and growth of e-commerce, the pharmaceutical industry has not been left behind with the introduction of pharmaceutical applications on mobile devices as well as websites. This 'new market frontiers' while demonstrative of the opportunities created by innovation it equally exposes a higher degree in vulnerability in the counterfeit pharma-sector. Counterfeiters now have at their disposal sophisticated distribution networks,<sup>238</sup> breaching national barriers and according anonymity with the attendant enforcement nightmare.<sup>239</sup> Business and the legal regime must adapt to this new threat. So what recommendations are available to enhance the efficacy of the anti-counterfeit regime in Kenya:

*First, scoping* the government must objectively review its policy approach, that appears to overzealously adopt an expansionist stance in the anti-counterfeit legislation.<sup>240</sup> This would be to ensure that pharma-IPRs are protected without unduly barring trade in the country and defeating realization of the Big Four Agenda.

In redefining its approach regard must be heard to the global IPR regime, to wit Kenya is a signatory. More specifically, the TRIPS Agreement sets out the minimum standards of protection in relation to IPRs including in effecting anti-counterfeiting legislation. Kenya's regime currently so broadly defines<sup>241</sup> the scope of counterfeits without any established value, unnecessarily distracting enforcement measures. This expanded scope has been declared

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<sup>237</sup>Inter-Agency Anti-Illicit Working Group Launched in Nairobi to Fight Trade in Counterfeits < <https://www.aca.go.ke/media-center/news-and-events/93-press-release-inter-agency-anti-illicit-working-group-launched-in-nairobi-to-fight-trade-in-counterfeits> > on 28 April 2019.

<sup>238</sup>Mallowah S, 'Why Kenya should set up fresh agenda to drive the war on counterfeits' <<https://www.businessdailyafrica.com/corporate/Kenya-should-set-up-fresh-agenda-to-drive-war-on-counterfeits/539550-2140008-glK0w4/index.html>

<sup>239</sup> <https://blog.cipit.org/2019/05/07/fakes-and-pirates-online-is-it-an-unregulated-space-in-kenya/>

<sup>240</sup><https://www.emeraldinsight.com/doi/abs/10.1108/03090560910935451?src=recsys&mbSc=1&fullSc=1&journalCode=ejm>

<sup>241</sup> Section 2, Anti-counterfeit Act, 2008.

unconstitutional before by the High Court of Kenya<sup>242</sup> and infact the National Assembly subsequently appropriately amended the impugned section.<sup>243</sup> Ergo, it is incredulous that the Kenyan Parliament reintroduced the unconstitutionally broadened scope of counterfeiting under Statute Law (Miscellaneous Amendment) No 18 of 2018, despite the Court's observations on the impact of the scoping on realization for the right to health.

As considered from the USA and RSA, the scope ideally ought to restrict itself to IPRs in the nature of trademarks and copyright of the one part; and, trademarks and copyrights that are registered and recognized in Kenya of the other. For purposes of this study, scope on pharma ought to be limited accordingly to pharma-trademarks registered in Kenya. The anti-counterfeit enforcement team would be better placed to effectively enforce a better particularized proscription, leaving pharmacovigilance and quality/standard verification to better equipped agencies such as the PPB and KEBS, allowing efficacy in the process.

*Secondly*, on capacity Kenya's regime includes any police officer, officers deputed to administer any IPR under any of the IPR registration or administration regimes; as an ACA inspector.<sup>244</sup> A distinction is drawn from the RSA approach that even in designating police officers a minimum rank (supposing a minimum level of training and experience); presumably on account of the broad powers conferred on anti-counterfeit enforcement officers.

It is also important to recognize that arguably, the biggest ill in Kenya which is the vice of corruption. This is because corruption cuts across all sectors and is thus a direct contributor to pharma counterfeiting in instance when bribes are taken to compromise enforcement measures, this cripples the fight against counterfeit pharma-goods.

Separately on lessons from RSA, the law imposes a mandatory requirement for warrants before action by ACA inspectors, but even more importantly the RSA law defines a mandatory 10 day period within which the inspector must present the matter before court, failing which the actions under the warrant are voided. In Kenya the inspectors enjoy a period of ninety days,<sup>245</sup> before presenting such matter before court – to insert the necessary impetus on the fight implementation of the ACA's mandate, this period ought to be reviewed as against the RSA provisions.

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<sup>242</sup> P.A.O and Another V AG and another (2011) eKLR.

<sup>243</sup> Statute Law (Miscellaneous Amendments) No 18 of 2014, "Delete the words "or elsewhere" wherever they occur in the definition of "counterfeiting"."

<sup>244</sup> Section 22(3), Anti-Counterfeit Act, 2008.

<sup>245</sup> Section 28(1), Anti-Counterfeit Act, 2008 laws of Kenya.

Another concern on the 2<sup>nd</sup> parameter, is the provision under the Section 34A, Anti-counterfeit Act<sup>246</sup> recordal of confessions by the ACA Executive Director from suspected counterfeiters. Subsequent thereto the ACA Executive Director has authority to issue penalties in the nature of fines and orders of destruction of seized property. Fundamental legal concerns arise from this provision, first the Act does not provide for an appellate mechanism, from the Executive Director's decision and penalty meted out, and that supposedly his decisions therein are final and may be enforced as a decree of the High Court. Secondly, despite being quasi-judicial proceedings there is no procedure or regulations on the recording of these confessions, exposing the suspect to possible coercion or undue influence with limited opportunity to challenge.

Additionally, the Act<sup>247</sup> creates the Intellectual Property Enforcement and Co-ordination Advisory Committee (IPECAC) but other than the apparent advisory role discernible from its title, the law fails to ascribe any distinct official roles. The law details that IPECAC comprises membership the Principal Secretary from the Ministry responsible for trade and 14 agencies involved in enforcement of IPRs. These 14 agencies are also not particularized under the law. From the examination of the Kenyan IPR legal regime, the need for coordination of multiple state agencies is apparent. However, the law therein does not provide for the formal engagement of specific agencies and this compromises the fight against counterfeit-pharma.

*Thirdly*, it is this paper's recommendation that in enhancing the efficacy of the anti-counterfeiting regime regard must equally be had to online environment. Indeed the difficulty in regulating this space cannot be gainsaid.<sup>248</sup> There is a growth in the uptake of internet usage and more particularly e-commerce in Kenya. Infact, the Communications Authority of Kenya is enjoined by law to facilitate the development of electronic commerce including through minimizing instances of fraud and barriers to the growth of this sector.<sup>249</sup> There is need therefore for this regime to specifically address the specificities that are associated with counterfeiting in the online market place.

As afore-urged Kenyans increasingly have wider access to the internet including through availed pharma-specific online platforms. This necessitates the need to ensure that authorities such as PBB have an online portal such as WHO Essential Medicines and Health Products

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<sup>246</sup> Section 34A, Anti-Counterfeit Act, 2008 (as amended in 2014).

<sup>247</sup>Section 16(4), Anti-Counterfeit Act, (as amended by Act 18 of 2014).

<sup>248</sup> Daily Nation, Thursday May 9, 2019; paid up advertisements by the Kenya Revenue Authority decrying the non-payment of taxes by business involved in online businesses; and in ability to accurately track them.

<sup>249</sup> Section 83C, 1(a), (c), (d) and (f) Kenya information and Communications Act, 1998.

Information Portal supports efforts to improve access to essential medicines and health products by making related, full-text articles available online.<sup>250</sup>

Further apt enforcement of IPRs at the online market place essentially invites the pharmaceutical companies in the fight against pharma counterfeiting. Indeed, these companies are called-upon to adopt self-help strategies<sup>251</sup> and mechanisms alongside the e-commerce platforms, to ensure they minimize as far as possible the offering for sale of counterfeit pharma online. These strategies would address detection, prevention and response mechanisms, and the strategies cannot be limited to legal but center on technological measures. The pharma companies must nonetheless be minded of the Streisand effect<sup>252</sup>, where in curbing the online counterfeit pharma; the potential unexpected effect of negative feedback from clients

The nuances of the online market place calls for enforcement of IPRs minded of the need to balance between consumer protection, asserting IPRs and facilitating trade. The growth of the online market place is certainly integral in facilitating international trade; however, it is necessary to adopt regulatory measures that do not bar trade but also do not compromise the legitimate interests including consumers' safety as well as the rights of IPR holders.

In linking the online enforcement measures to awareness creation (as significant strategy in curbing counterfeits), some companies urge that consumers in most instances aren't even aware that they are buying fake products; and seek to incentivize the consumers to purchase genuine by offering add-ons to their products.<sup>253</sup> But equally targeted at the consumers must be measures to ensure that the genuine pharma is affordable and readily available; this will help address the challenge posed by consumer accomplices.

The importance of this awareness creation and measures at addressing availability and access, is pertinent because consumers ultimately play a leading role in maintaining of counterfeit trade. It is therefore important to gain a deeper insight in the potential motives of consumers' willingness to purchase counterfeit products.

In summing up the above recommendations there is an underlying challenge on availability of requisite funding. A common hurdle in enforcement is always the issue of insufficient funding.

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<sup>250</sup> <http://apps.who.int/medicinedocs/>

<sup>251</sup> <https://blog.cipit.org/2019/05/07/fakes-and-pirates-online-is-it-an-unregulated-space-in-kenya/>

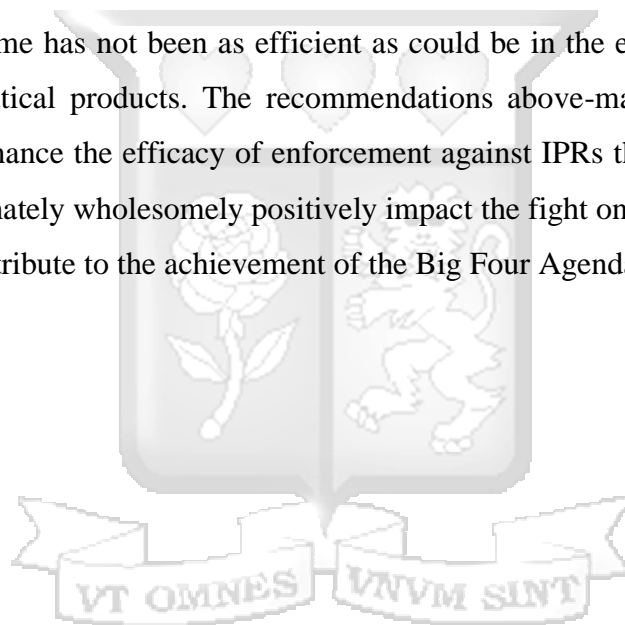
<sup>252</sup> The Streisand effect is a phenomenon whereby an attempt to hide, remove, or censor a piece of information has the unintended consequence of publicizing the information more widely, usually facilitated by the Internet. See <https://www.economist.com/the-economist-explains/2013/04/15/what-is-the-streisand-effect>

<sup>253</sup> <https://techtrendske.co.ke/philips-launches-buy-original-campaign-enlighten-consumers-existence-counterfeit-products/>.

The enforcement of IPRs with regards of pharma counterfeiting is certainly an expensive affair, the ACA was recently upgraded as a state Authority from an Agency, now referred to as the Anti-Counterfeit Authority from the hitherto Anti-Counterfeit agency<sup>254</sup> - *seemingly innocuous* - this change is significant in the ability of the now Authority to receive a higher budgetary allocation from government, and authorization to recruit a higher number of technical staff.

It would be fallacious however for this study to propound that an apt address of these 3 core challenges would, in and of themselves solely redress the challenges faced by the Kenyan pharma industry. It is this study's considered contention that there are numerous other enablers necessary to optimise the potential of this industry, however an apt anti-counterfeiting regime is at the heart of any such responsive measures.

In conclusion, this research confirms that indeed there exists an Intellectual Property Regime in Kenya but the regime has not been as efficient as could be in the enforcement of IPRs in respect of pharmaceutical products. The recommendations above-made establish that it is indeed possible to enhance the efficacy of enforcement against IPRs through a review of the legal regime and ultimately wholesomely positively impact the fight on pharma counterfeiting and consequently contribute to the achievement of the Big Four Agenda.



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<sup>254</sup> Statute Law (Miscellaneous Amendment) no 18 of 2018.

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