

# **Willingness and Ability to Use TRIPs Flexibilities**

## **Kenya case study**

Robert Lewis-Lettington

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September 2004

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The DFID Health Systems Resource Centre (HSRC) provides technical assistance and information to the British Government's Department for International Development (DFID) and its partners in support of pro-poor health policies, financing and services. The HSRC is based at the Institute for Health Sector Development's (IHSD) London offices and is managed by an international consortium of seven organisations: Aga Khan Health Services Community Health Department, Kenya; CREDES-International, France; Curatio International Foundation, Georgia; IDS (Institute of Development Studies, University of Sussex, UK); IHSD Limited, UK; IHSG (International Health Systems Group, Harvard School of Public Health, USA); and the Institute of Policy Studies, Sri Lanka.

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# Acronyms

AAK - ActionAid Kenya  
AIDS - Acquired Immune Deficiency Syndrome  
APIs - Active Pharmaceutical Ingredients  
ARV - anti-retroviral  
DFID - Department for International Development  
FDC - fixed-dose combination (in this study primarily in the context of ARV triple therapy)  
FPPs - Finished Pharmaceutical Products  
GMP - Good Manufacturing Practice  
GoK - Government of Kenya  
HAI - Health Action International  
HIV - Human Immunodeficiency Virus  
IPRs - Intellectual Property Rights  
KCAEM - Kenya Coalition for Access to Essential Medicines  
KEMSA - Kenya Medical Supplies Agency  
KIPO - Kenya Industrial Property Office. In 2002 KIPO became the Kenya Industrial Property Institute (KIPI) with its change in status from a government department to an autonomous parastatal.  
KIPI - see KIPO.  
MEDS - Mission for Essential Drug Supplies  
MoH - Ministry of Health  
MoTI - Ministry of Trade and Industry  
MSF - Médecins sans Frontières  
MSFB - Médecins sans Frontières (Belgium)  
NDQCL - National Drug Quality Control Laboratory  
NGOs - Non-Governmental Organizations  
PPB - Pharmacy and Poisons Board  
PSF - Pharmaciens sans Frontières  
TB - Tuberculosis  
TRIPs - Uruguay Round Agreement on Trade-Related Aspects of Intellectual Property Rights  
R&D - Research and Development  
SEAPRI - Southern Environmental and Agricultural Policy Research Institute  
WB - World Bank  
WHO - World Health Organization  
WOFAK - Women Fighting AIDS in Kenya  
WTO - World Trade Organization

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### Key words

- Drug registration
- Procurement
- Public health
- Legislation



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# Executive summary

As a developing country with relatively poor key health indicators, Kenya faces numerous challenges in the provision of effective health care to its citizens. The resurgence of public health problems such as malaria and tuberculosis and the emergence of the HIV/AIDS pandemic have placed considerable focus on the issue of access to medicines.

Kenya obtains medicines from two main sources: domestic and international. Local generic manufacturers play an important role, primarily for the public and not-for-profit sectors, but they face significant hurdles that do not encourage the substantial investment that would be required to expand to meet market needs and internationally recognised quality standards.

Kenya possesses a moderate pharmaceutical manufacturing capacity but relies on imports to supplement local sources of essential medicines. The imports are mainly from other developing countries, such as India, which have developed generic manufacturing industries in part because of case-specific extended grace periods under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). However, once these grace periods expire in 2005 it is expected that these importation options will be restricted.

Kenya is a developing country and a founding member of the WTO, while most of its foreign medicine suppliers are also WTO members. Key challenges in the delivery of essential medicines arise from the international intellectual property rights regime. This international regime provided the framework for the reform of Kenya's intellectual property rights legislation from 1999 to 2002 and access to medicines became a dominant theme in the reform process.

The Industrial Property Act, 2001, brought the country into compliance with TRIPs and contains key TRIPs flexibilities. The most widely used of these, and the subject of some controversy during the debate over the legislation, is a provision for parallel importation that exploits a very broad interpretation of the principle of the international exhaustion of rights, allowing even for the importation of legitimately produced and marketed generic medicines. There are also relatively orthodox provisions for voluntary and compulsory licensing and a somewhat innovative approach for governmental use orders that allows



for the initiation of the process by private individuals and institutions. Finally, there is a provision allowing the Minister for Health to declare the use of particular molecules or substances non-patentable on the basis of a serious health hazard exception.

Among related legislative and policy measures, the process for the registration of medicines is a potential barrier to access, particularly due to its largely unenforceable requirement for local clinical trials. Regional frameworks, such as the African Regional Intellectual Property Office (ARIPO), and trade agreements also have some potential to influence access to medicines in Kenya, although the possible directions of this influence are yet to fully emerge.

Kenya's ability to maximise the benefits of its relatively advanced legislation to promote access to medicines is limited and technical assistance to strengthen implementation efforts in various administrative authorities could encourage progress in this area. This limited capacity can be seen in the fact that Kenya has no strategy to adapt to coming changes in the international intellectual property framework and not even any detailed understanding of what these changes, and their impact, might be. The situation in Kenya suggests a number of specific conclusions as to future needs:

- support for local manufacturers to develop capacity and meet international standards
- capacity building in implementation of intellectual property and competition legislation
- review of competition legislation should harmonise with intellectual property legislation
- asymmetries in the treatment of importers and local manufacturers should be addressed
- voluntary licence legislation and practice should be reviewed
- medicines registration legislation and practice should be reviewed
- an assessment of the likely impacts of forthcoming changes in the international intellectual property rights framework should be considered



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# 1 Introduction

It is generally believed that in the first three decades of Kenya's independence, from 1963 to 1993, the country registered significant improvements in the provision of health services.<sup>1</sup> However, in the 1990s all key indicators, including the accessibility of primary health care services, mortality rates and life expectancy, began to decline. One aspect that did not change significantly was the variation in statistics in different regions of the country, with some having profiles similar to many middle-income countries and others being more reflective of the situation of the poorest least-developed countries and failed states. For example, in 2001 child mortality in Central Province was estimated at 27 per 1000 live births as opposed to 135 per 1000 live births in Nyanza and a national average of 71 per 1000 live births.<sup>2</sup> Several factors have contributed to the decline in key indicators. Chief among them has been the stretching of existing health infrastructure and stagnant budgets to an ever-expanding population, as Kenya's rate of population growth has exceeded its economic growth consistently for the last 20 years. Further exacerbating this situation has been deteriorating relationships between Kenya and its development partners as a result of concern regarding endemic corruption and political instability associated with the collapse of the one-party state in 1992 and the subsequent transition period, culminating in the transfer of power following the 2002 general elections.

Health care, in common with all public services, has been fundamentally affected by the economic situation of the country. The government provides an estimated 50% of formal health care services through public hospitals, clinics and dispensaries. A network of autonomous mission hospitals, supported by various religious denominations, provides an estimated further 40% of the total. The remaining 10% is provided by the private sector, although private facilities are almost exclusively restricted to the major urban centres. A large number of NGOs, well over 100, also provide a range of services targeting particular geographical areas or public health problems. Since the late 1990s all of the major health care providers, the exception being some of the NGOs, have charged some form of fees for their services.<sup>3</sup> While this was customary in the case of the private sector, it was much less common in public institutions and mission hospitals that traditionally provided care free, or, at a minimum, on the basis of a heavily subsidised, needs-based assessment. In the public sector, this change was the result of cost-sharing measures, introduced as part of structural adjustment programmes at the behest of the International Monetary Fund. In the case of mission hospitals, it was the result of the fact that the majority of such hospitals are now almost completely reliant on their own resources, with only limited support from their wider parent churches outside

the country. It should be noted that an estimated 70% to 80% of Kenyans, mostly rural, predominantly depend on traditional rather than formal medicine for their primary health care and have little or no access to secondary or tertiary care.

Within the health care sector, access to medicines has traditionally been considered within the context of broader issues of health care provision. However, the resurgence of, and emergence of drug resistance in historically problematic public health problems, particularly tuberculosis (TB) and malaria, together with the emergence of the HIV/AIDS pandemic over the last 20 years, has increasingly focused attention on the cost and supply of medicines. These questions have become particularly sensitive with the increasing enforcement of intellectual property rights since the enactment of national legislation in 1989 and the entry into force of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) in 1995. The opening of the review of the Industrial Property Act (1989), to comply with Kenya's TRIPs obligations, in 1999 triggered significant lobbying on the need to incorporate public health safeguards in the legislation. The general atmosphere, at times amounting to public outrage, was accurately summed up by the then Minister for Medical Services<sup>4</sup>:

*I think the Government's mood is that of the Member of Parliament who asked, 'How can we be denied access to drugs that prolong life when our people are dying?'*

*Hon. Dr. Amukowa Anangwe, EGH, MP<sup>5</sup>.*

While recognising that intellectual property rights were not necessarily the only barrier to the effective delivery of cheap and reliable medicines to the bulk of the Kenyan population, their significant influence in key sectors, such as HIV/AIDS and new treatments for drug-resistant malaria and TB strains, was recognised and led to comments such as that by the then Minister for Health:

*I hope that when the Intellectual Property Rights Bill comes to this House, we should put in it safety guards [sic] such as the parallel importation of drugs and how to overcome problems related to the generic formulations that would be cheaper.*

*Prof. Sam Onger<sup>6</sup>*

With intellectual property rights clearly at the centre of the debate, the subsequent review and enactment of the Industrial Property Act (2001) focused almost as much on access to medicines as it did on the need to comply with obligations under TRIPs.

This paper examines Kenyan legislation and policy in light of recent developments in the international intellectual property rights framework, in particular Paragraph 6 of the WTO's Doha Ministerial Declaration and the associated August 30<sup>th</sup> implementing

decision. It first considers the existing sources of supply, and associated trends in pricing, of pharmaceutical products in Kenya. Recognising that the scope of this paper is intellectual property rights, the paper places the primary focus on medicines that are, or are likely to be, affected by these rights. It then considers the existing legal structure and flexibilities contained therein to promote access to medicines. Associated with this discussion is consideration of closely related issues, such as regional and bilateral obligations and technical assistance issues. The paper then closes its substantive analysis by considering the specific question of the impact of the rapidly approaching 2005 deadline for all WTO members to provide patent protection for pharmaceutical products, the related August 30<sup>th</sup> decision and Kenya's response to these events.



## 2 Sources of supply and pricing/accessibility trends

The providers of health services in Kenya can generally be classified into three categories: public (government) hospitals, ranging from rural/up-country dispensaries to national referral hospitals; mission hospitals and NGOs offering health services<sup>7</sup>; and private hospitals. Each of these generally procure medicines from similar sources but follow different avenues, partly because of government policy in terms of procurement regulations, and partly because of individual institutional policies and needs.

The Ministry of Health regulates all government hospitals and procures medicines on their behalf. It does so by issuing tenders based on anticipated demand and in accordance with the Exchequer and Audit Act (Public Procurement Regulations). These regulations allow, *inter alia*, for a government ministry to employ the services of procurement agents and/or to directly tender for essential medicines under restricted conditions. The Ministry of Health utilizes these procurement procedures according to its particular needs, urgency and purpose. The procurement process employed by the Ministry of Health requires the winning bidders of a tender to deliver the essential medicines either directly to public hospitals or to the Kenya Medical Supplies Agency (KEMSA).<sup>8</sup> KEMSA in turn supplies public hospitals based on a “push” system, although current initiatives aim at moving this to a more demand driven, “pull” system.

The sources of essential medicines for public hospitals are varied and depend on the type of drugs procured, but include proprietary drugs imported from developed countries, generic imports, and generics produced domestically. Over the years the bulk of drugs supplied to public hospitals were imported from pharmaceutical industries based in developed countries. These sources from developed countries consist of two sub-categories: supply in fulfilment of contractual agreements with the Ministry, and donations. Generic manufacturers in other developing countries, especially India, have also been an important source of supply of essential medicines for public hospitals, second only to quantities supplied by pharmaceutical manufacturers in developed countries. Domestic generic manufacturers are a third source of supply for the Ministry of Health, but this has been by far the smallest. However, the government, since mid-2002, seems to be moving slowly towards increasing the supply quota for domestic generic manufacturers as recent tender awards have shown<sup>9</sup>, especially with regard to

what the local manufacturers can produce. Thus local manufacturers are currently said to be supplying the Ministry of Health with over 60% of the non-injectable essential drugs while over 80% of injectable vaccines are being sourced from pharmaceutical manufacturers in developed countries.<sup>10</sup>

Since June 2002, mission hospitals and NGOs have been relying mainly on generic manufacturers, both local and foreign (including European generic manufacturers),<sup>11</sup> as their source of essential medicines, though they also source branded medicines, depending on availability and needs and on the patent and registration status of the particular medicine. These hospitals and NGOs are not bound by the government procurement regulations and instead rely on intermediaries to procure their requirements. Mission hospitals procure their essential drugs mainly through Mission for Essential Drugs and Supplies (MEDS)<sup>12</sup>, while most NGOs procure from Centrale Humanitaire Medico-Pharmaceutique (CHMP), a non-profit organization affiliated to Pharmaciens San Frontières (PSF).

Unlike public and mission hospitals, private hospitals procure medicines on an individual institutional basis. One of them, Mater Hospital, has a policy of stocking a generic version for every branded drug and of using a 'just-on-time' supply system. This means that little drug stock is usually held. The sources are mainly pharmaceutical industries in developed countries, most of which have local marketing offices or distributors, and Indian and Chinese generic manufacturers through their local distribution agents. The level of supply from local generic manufacturers is low. Because private hospitals are profit-making entities, they do not generally engage in sourcing essential medicines directly from manufacturers, partly because of efficiency and human resource reasons and partly because of their policy of concentrating on their core business - treatment.

## **2.1 Domestic Supply**

Kenya's generic manufacturing industry is characterized by an investment worth over US\$40 million by the three most active pharmaceutical manufacturers.<sup>13</sup> These pharmaceutical manufacturers have been operating in an environment characterized by poor economic growth over the last decade.<sup>14</sup> The last decade also witnessed an increased incidence of absolute poverty, especially between 1994 and 1997. It is estimated that over 50% of its population live below the poverty line.<sup>15</sup> Its productive enterprise R&D investment per capita is less than 1 US cent and patents per 1,000 people falls below 0.0001.<sup>16</sup> Aggregate R&D activity is therefore very low and this restrained environment in turn constrains domestic pharmaceutical manufacturers.

The relatively small domestic pharmaceutical industry in Kenya is beset by a number of problems that make it difficult to grow and to become more competitive nationally and



regionally. Although the pharmaceutical industry is characterized by a large number of registered manufacturers, mostly based in Nairobi and its environs,<sup>17</sup> only close to a third of these are actively engaged in the actual manufacture of drugs, particularly generics: Cosmos Limited, Laboratory & Allied Limited, Elys Chemical Industries Limited, Regal Pharmaceuticals Limited, Biodeal Laboratories Limited, Pharmaceutical Manufacturing Company, Beta Healthcare International Limited, Nairobi Enterprises Limited and Universal Pharmacy (K) Limited.<sup>18</sup> Whereas the Kenya Essential Drug List heavily influences their product lines,<sup>19</sup> local production capacities are hampered by a myriad of internal factors, such as ageing manufacturing facilities and use of obsolete or inefficient technologies.<sup>20</sup> Moreover, these local manufacturers have very limited production capacity and engage in minimal research and development. What R&D there is in the pharmaceutical sector is restricted to innovation in manufacturing processes rather than innovative pharmaceutical products.

The main external factor impeding expansion of local production capacities is non-availability of local primary, secondary and tertiary ingredients. Local manufacturers do not possess technology to refine pharmaceutical raw materials to acceptable pharmaceutical standards. Thus almost all active pharmaceutical ingredients (APIs) are imported from India, China and other developing countries. The cost of production is also generally high due to poor infrastructure and an antiquated communications system. Electricity, the only source of industrial energy, is also very costly.<sup>21</sup>

Inadequate market-size or “lack of a market”<sup>22</sup> is also an oft-cited factor. In seeking efficient economies of scale for a number of products, Kenyan manufacturers often need to supply both Kenyan and non-Kenyan markets. Exacerbating the market-size problem is that none of the local generic manufacturers are WHO pre-qualified.<sup>23</sup> Thus, even with Kenya being a beneficiary of the Global Fund to Fight Tuberculosis, Malaria and AIDS (GFTAM) and World Bank (WB) health programmes, the Ministry of Health will not be able to source locally-produced drugs using funds from these programmes after December 2004. Instead, procurement from the local generic manufacturers will be limited to funds allocated in the national budget.

As a source of supply for essential medicines, increased local production could have favourable effects on availability, but unfavourable effects on affordability, given current cost disadvantages in the industry. With regard to availability, the fact that most of the essential medicines have to be imported means that in the event of shortages from the foreign sources, local industries cannot cover the shortage; this problem occurs frequently. The case for affordability of locally-produced medicines is largely negative - the lack of capacity to manufacture pharmaceutical ingredients and high production costs impact negatively on price, and ultimately on quantity. Both these factors will be exacerbated in the near future when the Protocol on the Establishment of the East Africa

Customs Union comes into force later in 2004<sup>24</sup>. The Protocol proposes, under Article 11, to impose a 10% tax on goods imported into the Union, and also on goods from Kenya exported to Uganda and Tanzania. If importers of essential medicines and APIs will pass this tax burden to the consumers, then prices of these medicines will increase. This tax will, however, be phased out gradually over a period of five years from the date the Protocol will come into force.

## 2.2 International Supply

In general terms, international supply of pharmaceutical products into Kenya can be classified into two categories: as a source of supply of APIs for local generic manufacturers and as a source of finished pharmaceutical products (FPPs), whether branded or generics. As stated earlier, APIs are not locally manufactured and thus all pharmaceutical generic manufacturers in Kenya rely on foreign API sources, mostly from India and China. This has a cost and price effect on the generic FPPs manufactured locally.

FPPs sourced internationally, either proprietary or generic, can be further sub-classified as purchased or donated.

As stated earlier, international FPPs, both brand name and generic, are the main source of supply of essential medicines in Kenya. Brand name or proprietary FPPs are ordinarily considerably more expensive than their generic counterparts, but generic equivalents are ordinarily not available for on-patent medicines. The market price of imported FPPs is based on several factors including patent status, number of competitors, cost, insurance and freight (CIF) costs, tax and duties<sup>25</sup> paid at the point of entry, distribution and storage costs related to importation. This complex system of costs certainly affects the affordability of essential medicines.

Apart from cost issues, shortages of essential medicines, particularly anti-retrovirals (ARVs), occur frequently, particularly in government hospitals. For example, in early March 2004 most public and private hospitals experienced a shortage of efavirenz (brand name *Stocrin*), a drug manufactured by Merck and used in ARV treatment. For HIV/AIDS patients, constant availability of ARVs is essential for treatment efficacy. Shortages, which in turn affect adherence to treatment, can lead to serious potential consequences ranging from development of resistance to first line treatments to, ultimately, death of HIV/AIDS patients.

Donated FPPs cause market distortions that can affect choice of treatment regimes, the emergence of competitive markets, and the long-term costs of treatment. Accordingly, pharmaceutical donations are highly scrutinized and their long-term costs must be



weighted against any short-term gains. In this regard, it is particularly important to note that drug donations can deter expansion of the local pharmaceutical industry and/or the development of a foreign generic industry that can sustainably supply procurement needs on an affordable basis.<sup>26</sup>



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## 3 Existing legislation and practice

In 1998/1999 the Kenya Industrial Property Office (KIPO, since renamed the Kenya Industrial Property Institute, or KIPI) began to take steps to review the 1989 Industrial Property Act<sup>27</sup> to fulfil the country's obligations under the WTO's<sup>28</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). Access to medicines became one of, if not the, main issues in the review of the Act with a wide range of stakeholders<sup>29</sup> actively lobbying the Ministry of Trade and Industry, lead agencies, and Parliament over a period of some three years. Civil society<sup>30</sup> was most prominently represented by the activities of the Kenya Coalition for Access to Essential Medicines (KCAEM),<sup>31</sup> a loose coalition of institutions and individuals that initially formed around the review of the Industrial Property Act. The position advocated by KCAEM was based on a published technical report commissioned by Médecins sans Frontières' (MSF) Access to Essential Medicines Campaign.<sup>32</sup> The private sector, in particular multinational pharmaceutical companies, is also believed to have intervened. These interventions were less public and appear primarily to have been achieved through proxies such as local law firms<sup>33</sup> and the diplomatic representatives of key developed countries.<sup>34</sup>

### 3.1 TRIPs Compliance

As a developing country member of the WTO, Kenya was required to implement TRIPs-compliant legislation within five years of the entry into force of the Agreement, that is by 31<sup>st</sup> December 1999. Somewhat belatedly, the Kenyan Parliament passed the Industrial Property Act in 2001 (IP Act 2001). The Act was given Presidential assent in July 2001 and was subsequently published in August 2001.<sup>35</sup> The Act came into force by notice on 1<sup>st</sup> May 2002.<sup>36</sup>

The IP Act 2001 incorporates the majority of recognized TRIPs-compatible access to medicines safeguards, including an expansive interpretation of the principle of international exhaustion of intellectual property rights (IPRs), rights of government use, and the issuance of compulsory licences. The Act also contains provisions on the *Bolar* limited exception and discretionary restrictions on patents whose subjects may be used to address serious health hazards.<sup>37</sup> TRIPs provisions relating to "mailbox" legislation for post-1995 pharmaceutical product patents, Articles 70.8 and 70.9, are not applicable to Kenya as the Industrial Property Act (1989)<sup>38</sup> already provided for these.



During the review of Kenya's patent legislation in the Council for TRIPs, no questions were raised with respect to the aforementioned flexibilities; accordingly, the Kenyan legislation may be judged to be generally TRIPs compliant.<sup>39</sup>

In addition to its core intellectual property rights elements, the IP Act 2001 also incorporates an element of competition law, primarily by empowering the Managing Director of KIPi to recommend the issuance of a government use order by the Minister for Trade where the Managing Director determines that the manner of exploitation of an invention by the owner of a patent, or licensee thereof, is not competitive.<sup>40</sup> Given that due process and a right of appeal are provided for in these provisions, the IP Act 2001 can be judged as TRIPs compliant in this regard. However, in addition to the competition-related provisions of the IP Act 2001, Kenya also has specific competition legislation in the form of the Restricted Trade Practices, Monopolies and Price Control Act.<sup>41</sup> This legislation establishes the office of Commissioner of Monopolies and Prices, providing broad authority over competition matters, but does not provide for any measures distinguishing between the respective mandates of the Commissioner and the Managing Director of KIPi as regards competition issues in intellectual property rights. Given that both offices understand their mandates as including competition and intellectual property matters,<sup>42</sup> there is considerable scope for conflict. The Restricted Trade Practices, Monopolies and Price Control Act (1989) is currently under review and it remains to be seen whether it will specifically address intellectual property matters and, if so, whether its harmonisation with the IP Act (2001) will be considered.

### 3.2 Parallel Importation

Pre-2002: All forms of parallel importation prohibited

Post-2002: Broadest possible interpretation of parallel importation – brand name products and legitimately marketed generics included

May/June 2002: Parallel importation of generic pharmaceutical products, in particular anti-retroviral triple therapy, begun by the non-profit sector – prices to patients fall by between 40% and 65% overnight

Kenyan law and policy on parallel importation has been extraordinarily fluid and a touchstone of Kenyan attitudes to access to medicines since mid-1999. Pursuant to Section 36 of the then in-force Industrial Property Act (1989):

36. The owner of the patent shall have the exclusive right to preclude any person from exploiting the protected invention by any of the following acts -

- (a) when the patent has been granted in respect of a product –
  - i) making, importing, offering for sale, selling and using the product; or
  - ii) stocking such product for the purposes of offering it for sale, selling or using the product;

The 1989 text prohibited all forms of parallel importation, making Kenya a segmented market and thereby allowing patent holders to control all aspects of the national market for patented products.<sup>43</sup> Prices and availability were insulated from the world market and there was no form of alternative supply or other competition for on-patent products.

The question of parallel importation became one of the key lobbying points for civil society organizations and international NGOs during the review of the Industrial Property Act due to its potential to provide immediate results<sup>44</sup> in terms of lower pricing, improved stability of supply, and generally enhanced competition. The Industrial Property Bill (2001) proposed a change from Kenya's previously restrictive legislation in the form of a provision reflecting an orthodox interpretation of the concept of international exhaustion:

58.2 The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya by the owner of the patent or with his express consent.

This text matched the minimal option proposed by civil society organizations to allow parallel importation of brand name products. However, discussions with stakeholders and politicians<sup>45</sup> suggested that a more expansive interpretation of international exhaustion, that would provide access to lower-priced generics,<sup>46</sup> might be acceptable. As a result, the KCAEM<sup>47</sup> proposed a text based on a more aggressive interpretation of the principle of international exhaustion<sup>48</sup> that, given the ambiguities regarding the concept,<sup>49</sup> was nonetheless regarded as TRIPs compatible:

58.2 The rights under the patent shall not be enforceable against any person who imports or in any way deals in the patented product, or a product obtained by the patented process, once the said product has been lawfully placed on the market in any country with the consent of the owner, a licensee or any other authorised person

This text would have allowed for the parallel importation of brand name products, generics produced under voluntary or compulsory licences and, arguably, generics produced in countries where the brand name was not the object of patent protection (this last possibility was by far the most controversial).

As it was the Industrial Property Bill text that went to Parliament for debate and adoption, attention focused on the closing language of sub-section 58.2, "...by the owner of the patent or with his express consent". During Parliamentary debate a proposal was made to amend this to, "...by the owner of the patent or with his express consent or by any other authorised person." This amendment would have effectively introduced the



same concept as that proposed by the KCAEM. Debate on this proposal concluded with the deletion of all the language that was its subject<sup>50</sup> and produced the following text in the IP Act (2001):

58.2 The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.

This text entered into force on 1<sup>st</sup> May 2002, pursuant to the commencement date published by the Minister for Trade and Industry.<sup>51</sup> There was some concern that this text did not prevent the importation of pirated or otherwise illegal products by removing all references to who places a product on the market. However, the apparent understanding of Parliament, and the interpretation subsequently adopted by regulatory bodies and other stakeholders, was that Parliament would not sanction an illegal act, whether in its jurisdiction or otherwise. This understanding was confirmed by Clause 37 of the Industrial Property Regulations (2002), which provides that:

The limitation on the rights under a patent in section 58(2) of the Act extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market.

Upon the entry into force of the 2001 Act, several non-profit organizations prepared to place orders for the import of generic drugs, particularly anti-retrovirals and treatments for opportunistic infections associated with HIV/AIDS. However, on 4<sup>th</sup> June 2002 an amendment to the 2001 Act that had been included in the Statute Law (Miscellaneous Amendments) Act, 2002, entered into force:

58.2 Delete the fullstop at the end thereof and add the words "by the owner of the patent or with his express consent".

The Statute Law (Miscellaneous Amendments) Act, 2002, contained numerous contentious issues<sup>52</sup> and was passed late at night when most MPs were absent, and key activists<sup>53</sup> on access to medicines issues were out of the country. This amendment blocked the planned parallel importation of generic drugs by NGOs. The amendment was contrary to the Parliamentary rule that no amendments should be permitted to any Act prior to six months after its entry into force and the Minister for Trade and Industry, KIPi and the Attorney General's Chambers all stated that they had not been its source.<sup>54</sup> Once the amendment came to the attention of MPs, the Minister for Trade and Industry, the Vice President (as Chairman of the Parliamentary Business Committee) and the Parliamentary Health Committee vowed to reverse it forthwith and to instruct the relevant authorities not to enforce it pending reversal. In an unprecedented move, the amendment was reversed in August 2002.

The first parallel importation of generic drugs under the 2001 Act occurred in early June 2002. This was a symbolic shipment of anti-retrovirals and drugs for the treatment of HIV/AIDS opportunistic infections imported by MSF and AAK from India for use in MSF's clinics providing free treatment. However, this importation was rapidly followed by a significant order from MEDS to be distributed at cost through mission hospitals. MEDS has since continuously relied on parallel importation of generics for some of its key drugs affected by intellectual property rights, in particular anti-retrovirals, and the public sector has recently also begun to take advantage of this mechanism.

### 3.3 Voluntary Licensing

- Voluntary licences regulated to prevent abusive conditions
- Must meet statutory conditions and be approved, and registered, by KIPi
- Weak enforcement
- No evidence of use in pharmaceutical sector – perhaps due to lack of pressure on potential licensors

Voluntary licences, referred to in the IP Act 2001 as contractual licences, play two roles under Kenyan industrial property law. The first is in relation to other mechanisms, namely compulsory licensing and governmental use, and the second is as a substantive mechanism in their own right. Sections 3.4 and 3.5 of this paper consider, *inter alia*, the role of voluntary licences in compulsory licensing and governmental use respectively. This section focuses on legal provisions relating to the use of voluntary licences as a substantive mechanism in their own right.

The IP Act 2001 lays down various conditions and procedures that must be followed for the valid issuance of a voluntary licence. These conditions and procedures are characterized by a concern over the potential for abuse in voluntary licensing, a concern common to many jurisdictions. The basic principle of voluntary licences is that a licensee may, subject to contrary or limiting terms in the contract, be granted rights similar to those of the patent holder or any subset thereof. While this is somewhat inescapable (i.e. one cannot license rights greater than those that one possesses), it is the statutory conditions imposed upon the verification and terms and conditions of licenses that potentially raise questions, including in relation to access to medicines. The condition of verification is that all voluntary licence agreements must be registered with KIPi and KIPi has authority to refuse registration and thereby invalidate any licence contract if it is not satisfied with some or all of the terms and conditions of the voluntary licence. Thus, inasmuch as KIPi is not a party to the licence *per se*, experience in other sectors suggests a need to involve KIPi, albeit on an informal basis, in the negotiations between an applicant and a patent owner to avoid registration problems upon execution of the licence. KIPi's inclusion in the negotiation process on an informal basis has several

implications that may be problematic to potential licensors, not least as regards the disclosure of confidential information. The requirement of KIPi's approval of the terms and conditions of any licence leads to the more specific requirements of the IP Act 2001. The Managing Director of KIPi's acceptance or rejection of any licence is linked to a number of specific conditions but also allows for more discretionary refusal where the Managing Director *is of the opinion that any clause in a licence contract imposes unjustified restrictions on the licensee with the consequence that the contract, taken as a whole, is harmful to the economic interests of Kenya.*<sup>55</sup> The statutory conditions guiding the Managing Director's decision are primarily provided for in section 69, which contains 33 separate prohibitions. While it would be difficult to consider the implications of all of these prohibitions here, a number of potential relevance to access to medicines are provided as an illustration:

69. The Managing Director may refuse to register a licence contract if...the effect of any...term contained in the contract is –
- (ii) to require payment of a price, royalty or other consideration which is disproportionate to the value of the technology to which the contract relates;
  - (iii) to require the licensee to acquire any materials from the licensor or from sources designated or approved by him, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;
  - (viii) to limit the volume of the products produced by the licensee with the help of the technology to which the contract relates;
  - (ix) to restrict or prohibit the export of the products produced by the licensee;
  - (xi) to impose restrictions on research or technological development carried out by the licensee to absorb or adapt the technology in connection with new products, processes or equipment;
  - (xiv) to fix prices for the sale or resale of the products produced by the licensee with the help of the technology to which the contract relates;
  - (xvii) to require that disputes arising from the interpretation or performance of the contract be governed by a law other than the law of Kenya or that such disputes be brought before courts located in a country other than Kenya;
  - (xxvi) to impose restrictions which prevent or hinder export by means of territorial or quantitative limitations or prior approval for export or export prices of products or increased rates of payments for exportable products resulting from the technology licensed;
  - (xxvii) to impose quality control methods or standards not needed by licensee, except to meet the requirement of a guarantee or when the product bears a trade mark, service mark or trade name of the licensor;
  - (xxxi) to require payment of royalty for patents granted outside Kenya;

Experience in the use of voluntary licences in the Kenyan pharmaceutical sector to date is extremely limited. Prior to the amendment of Kenya's provisions regarding the exhaustion of rights, discussed in section 3.2 above, any import, use, sale or stocking of a patented product by an entity other than the patent holder would have required a licence. Thus the local subsidiaries and distributors of multinational companies should have reached licensing agreements with those multinational companies and have had these approved and registered by KIPi.<sup>56</sup> This has not been the case, calling into question the enforceability, or political will to enforce, the statutory conditions regarding voluntary licences. As a result of this situation, it seems unlikely that the registration requirements and statutory restrictions relating to voluntary licences have any significant influence on voluntary licensing in Kenya.

Perhaps the main concern relating to voluntary licensing and access to medicines is the fact that no Kenyan generic manufacturer has, as far as the authors have been able to determine, yet been granted a voluntary licence by a brand name manufacturer. In the absence of evidence of any significant influence from the regulatory regime, this situation appears to partly result from a lack of requests from local manufacturers, usually ascribed to either lack of capacity<sup>57</sup> or concern at the political implications of a request.<sup>58</sup> However, it can also, at least partly, be ascribed to the fact that, where requests for voluntary licences are known to have been made,<sup>59</sup> potential licensors have either declined to reply or have replied requesting sensitive commercial information or virtually impossible requirements as conditions for the grant of a licence.<sup>60</sup> This lack of cooperation may, at least in part, be the result of concerns as to local infrastructure and capacity,<sup>61</sup> particularly as regards quality control issues, but seems likely to also be influenced by a lack of pressure to cooperate.

### 3.4 Compulsory Licensing

- Two forms of compulsory licence:
  - Supply on reasonable terms
  - Interdependence of patents
- No compulsory licences ever issued
- Confusion between compulsory licences and governmental use orders

The IP Act (2001) provides for the granting of compulsory licences in sections 72 through to 78. These provisions largely reflect a trimmed down version of sections 95, 96 and 98 through to 102 of the 1989 Act.

Sections 72.1 and 73.1 provide the two possible grounds for the granting of compulsory licences. Section 72.1 of the Act provides that an applicant for a compulsory licence may



apply to the Industrial Property Tribunal<sup>62</sup> “on the grounds that a market for the patented invention is not being supplied on reasonable terms in Kenya”. This provision is effectively a hybrid of traditional working requirements and competition measures, requiring that a product be both supplied and on reasonable terms. Section 73.1 provides that a compulsory licence may be granted, to the extent necessary, in respect of a patented invention upon which the working of a later patented invention is dependent where the later patented “invention constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent”. A good example of the need for Section 73.1 in the context of access to medicines is the case of ARV triple therapy fixed dose combinations (FDCs). The majority of the constituent components of these FDCs are protected by patents held by different companies. In countries where these patent rights are valid, a manufacturer would need either the cooperation of all the patent holders or a compulsory licence such as that provided for by Section 73.1 to produce FDCs.<sup>63</sup>

Several conditions are imposed on the grant of a compulsory licence:

Section	Condition
72.2	<p><b>Specific to 72.1</b></p> <p>A compulsory licence may not be granted where the owner of the patent demonstrates that “circumstances exist which justify the fact that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Kenya”.</p>
74.1(a)	<p><b>General Application</b></p> <p>The applicant must demonstrate that they have requested a voluntary licence and have either been refused reasonable commercial terms or have not received a response within a reasonable time. <i>This condition may be waived in the case of “national emergency or other circumstances of extreme urgency” (74.2).</i></p>
74.1(b)	<p>The applicant must offer guarantees that they will remedy the deficiencies or satisfy the requirements that gave rise to the application</p>

In addition to these conditions, a number of terms are statutorily imposed on any grants of compulsory licences:

Section	Term
	<b>Specific to 73.1</b>
73.1	Limited to “the extent necessary for the working of the invention”
73.2	The holder of the patent for which the licence is granted is entitled to a reciprocal “cross-licence” on the new patent
73.3	The compulsory licence may only be transferable with the transfer of the dependent patent
	<b>General Application</b>
75.1	The Tribunal may fix terms that “shall be deemed to constitute a valid contract”
75.2(a)	Licence is limited in scope and duration to the purpose authorised
75.2(b)	Licence is limited predominantly for the supply of the domestic market
75.2(c)	Licensee may not grant subsidiary licences
75.2(d)	Non-exclusivity
75.2(e)	Patent holder must be remunerated in an equitable manner “with due regard to all the circumstances of the case, including the economic value of the licence
76	Licences may only be transferred with the business of the licensee with which they are associated

Section 77 contains several measures relating to the cancellation of compulsory licences. Sub-sections 77.1(a) and 77.2 are related in that they provide for the cancellation of a licence, both upon application, but the former by “any interested party” and the latter by the Minister or the patent holder, where a licensee either fails to comply with the terms of the licence or fails to “remedy the deficiencies or satisfy the requirements which gave rise to his application”. The issue addressed by 77.2 is a required term in a licence under 75.2(a) and thus, effectively becomes a component of 77.1(a). In addition, 77.1(b) provides for the cancellation of a licence, upon application by any interested party, in the event that “the conditions which justified the grant of the licence have ceased to exist and are unlikely to recur”. This provision is also largely catered for by 77.1(a), as 75.2(a) requires that it be a term of any licence, but it also



contains a key distinction requiring “that the legitimate interests of the licensee are adequately protected”. This is understood to allow for situations such as the recovery of capital investments made by licensees to fulfil licence terms and conditions. Sub-section 77.3 does not refer to cancellation and allows for the variation of the terms of a licence where this is justified by new facts.

The final key point in regard to compulsory licences is that Section 115.1 provides that “any order or decision of the Tribunal” may be appealed to the High Court. Such appeals could include the basic grant or refusal of a licence or components thereof, such as specific terms and conditions.

The various provisions of the 2001 Act relating to compulsory licences leave a number of questions unanswered, some of which may come to be significant and others not. The following discussion is not intended to be exhaustive, as this is probably impossible in a speculative exercise, but presents some of the concerns that have been raised by stakeholders or that are, in the opinion of the authors, of potential importance to the issue of access to medicines.

First, the grounds for the granting of compulsory licences are somewhat ambiguous. Section 72.1 refers only to a requirement that “...a market for the patented invention is not being supplied on reasonable terms in Kenya”. The ambiguities lie in the terms “market” and “reasonable”. These may appear to be straightforward concepts but detailed analysis demonstrates the need for policy guidance. For example, do the majority of Kenyans who could probably not afford more than a few hundred Kenyan shillings per month for treatment such as ARV triple therapy constitute a market? If they do, should the meaning of “reasonable terms” be determined by the needs of the market, the needs of the patent holder or by some combination of the two? An additional ambiguity is introduced to the provisions in Section 72.1 by the text of 72.2, referring to the defence of a patent holder against the grant of a compulsory licence where “circumstances exist which justify the fact that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Kenya”. The corresponding provisions of the 1989 Act simply referred to the legally familiar concept of *force majeure*<sup>64</sup> and, while not explicit, the 2001 text may imply a broadening of this concept to include events over which the patent holder has some influence or control, thereby further limiting the scope for the grant of compulsory licences. In addition, the grounds for the grant of a compulsory licence on the basis of the interdependence of patents, provided for in Section 73.1, imply, or even explicitly iterate, a bias towards patented inventions. To use the example of FDCs, consider the situation where an FDC is not patented in Kenya but one or more of its component compounds are. In such a situation, the FDC cannot be used as grounds for an application for a compulsory licence under Section 73.1, thereby prohibiting manufacture of the FDC. This is a

serious defect that should be promptly addressed. Also in relation to Section 73.1, the use of the term “economically significant” is ambiguous. Would an FDC be considered of considerable economic significance in comparison to the use of individual ARVs? It is clearly significant in terms of public health but does it fall within the scope of “economic”, a term that has been a subject of academic debate for decades?

Second, not all of the mandatory terms and conditions of compulsory licences are clear. Since President Moi’s informal declaration of HIV/AIDS as a national disaster in 1999<sup>65</sup>, the provisions of Section 74.2 have been the subject of much debate among stakeholders. More specifically, the questions of whether the recognition of a “national emergency” requires an official notice to that effect and what might be an “other circumstance of extreme urgency” have been discussed without any clear resolution. In the latter case, the question of who is competent to decide what constitutes “extreme urgency” is also unclear. In Section 75.2(e), it is not clear what “all the circumstances of the case” might be. In particular, the issue of “the economic value of the licence” raises questions when considering access to medicines for the treatment of HIV/AIDS, opportunistic infections and other chronic health problems such as malaria and TB. The patent holders of many of these drugs state that they are providing them to Kenya, and other countries, at cost, so does this mean that the economic value of the licence is zero? Economic value to whom: the patent holder, the prospective licensee, the country or to the patient?

Third, somewhat predictably given its recent provenance, the Kenyan legislation does not currently address the issue of importation (or export) pursuant to the WTO Paragraph 6 Implementation Waiver of August 30, 2003. Admittedly, Kenya has options to import generic medicines pursuant to its liberal parallel importation rule and it may continue to import pre-1995 generics produced lawfully in India or elsewhere. But the window for purchasing newer generic drugs is closing and thus the August 30<sup>th</sup> Agreement may be one of the few options available for purchasing the latest medicines at lower costs. This may also impact on the domestic generic manufacturing industry, as the same issues that affect the importation of FPPs also affect APIs and related products.

Fourth, and last, is a question of major importance to the subject of this study: namely whether there are TRIPs-compliant flexibilities to export medicines to other developing countries, especially in the African region. At present, compulsory licences are not legislatively authorized for the export of medicines pursuant to Paragraph 6 of the Doha Declaration and the subsequent August 30<sup>th</sup> decision. (The position of KIPi is that they are not, at least where the primary purpose of the licence is for such exports, due to the restrictions imposed by 75.2(b).) But KIPi is examining options to amend the 2001 Act to allow for quantity-specific exports pursuant to a compulsory licence. (Passage of such amendment is a matter of some urgency to the extent that Kenya wants some of its local



producers to become regional suppliers.) However, previous discussions over options for the importation of generic drugs for use by the non-profit sector<sup>66</sup> suggest a possible loophole that would also allow for at least the limited export of medicines. This is the invocation of Section 58.1, which provides that “[t]he rights under the patent shall extend only to acts done for industrial or commercial purposes...”. If a compulsory licence were issued for the manufacture of medicines for export, particularly if for export to the public or other non-profit sector in the country of destination, would this constitute “industrial or commercial” purpose in Kenya? Kenyan jurisdiction ends at its borders and the market impact of the exportation would be in the country of destination, not Kenya. To recognise the force of Section 58.1 over exports could thus be said to imply an extraterritorial application of Kenyan law that is at once unusual and, more specifically, at odds with the fundamental principle of the national, or territorial, nature of intellectual property rights.

Discussion of compulsory licences in Kenya has been somewhat dry and analytical, and the analysis somewhat speculative, due to the fact that there are no precedents expanding upon, or providing details regarding, the provisions of the legislation. No compulsory licence has ever been granted and it appears that no applications have ever proceeded beyond preliminary enquiries. It is not clear why this is the case, with potential applicants citing the complexities and uncertainties of application procedures and the authorities citing a dearth of applications.<sup>67</sup> It is entirely possible that both views are correct and that the problem is one of awareness and capacity relating to compulsory licences. This could, perhaps, be partly addressed by the establishment of a clear policy by the relevant authorities (KIPI and the Minister) and by capacity building activities among potential applicants and local IP lawyers. The lack of awareness and capacity is highlighted by the fact that the one case of an application for a compulsory licence that has come to public attention, including by the mainstream media, is not actually an application for a compulsory licence. The application was submitted, in 2003, for the local production of ARVs by a generic manufacturer, Cosmos Pharmaceuticals Ltd. However, the application was submitted to the Minister for Trade and Industry, and not the Tribunal, to allow Cosmos to fulfil the provisional award of a tender by the Ministry of Health. Thus, it is clear that the application was actually for a government-use order, something discussed in the next section of this study.

### 3.5 Governmental Use

- Grounds for issue - general public interest and anti-competitive practices
- Rights may be granted for any purpose to any legal or natural person
- May be without compensation – this may be unconstitutional
- May be initiated by the Minister or by private individuals
- Relationship with voluntary licences unclear
- Never been invoked – one application pending

The government-use provision in the IP Act 2001<sup>68</sup> grants the Minister for Trade and Industry wide powers to assert the government's right to take and use protected technology in the public interest.<sup>69</sup>

Section 80 lays down two grounds upon which the government can exercise authority over a patented invention without the authority of the patent holder. First, where the public interest in national security, nutrition, health, environmental conservation, or the development of other vital sectors of the national economy so requires, the Minister may, upon application to him by any person and after consultation with KIPi and the patent holder, order that the protected invention be exploited by the government or its appointee. This governmental use is subject to the payment of adequate compensation<sup>70</sup>. Second, where the Managing Director of KIPi determines that the manner of exploitation of an invention by the owner of the patent or his licensee is not competitive, he may recommend that the Minister issue a government-use order on terms similar to those under which the Minister may issue an order on public interest grounds.<sup>71</sup>

The wide powers and discretion granted to the Minister are codified in four ways. First, the text uses the word "may" rather than "shall", connoting that the Minister is not necessarily bound by the text in interpreting what the text means. This is confirmed by Section 80.1(A), which says that the Minister does not necessarily have to follow the procedures set in the section in making his determination on government use. Second, Section 80.1 does not define what "exploitation" is. However, Section 80.1(A) states that the Minister may authorize the "importation, manufacture or supply, or authorize the utilization of any molecule or substance by any person..." Third, it is clear from the text of Section 80 that the Minister has power to grant the order to any person, ranging from a government ministry or agency to independent natural and legal persons. Fourth, the government-use provision is not restricted to product patents; orders may be issued against process patents as well.<sup>72</sup>

The government-use provision lays down various grounds and processes that must be followed in the issuance, variation, cancellation, and appeal of a Ministerial decision to issue a government-use order. However, the procedure set is somewhat unclear and the exercise of some of the powers conferred upon the Minister border on unconstitutionality. Four examples highlight these concerns.

First, the Managing Director of KIPi is granted powers to determine that the exploitation of an invention is not competitive. How the Managing Director would go about this is not stipulated. While the Restrictive Trade Practice, Monopolies and Price Control Act<sup>73</sup> generally confers equal and similar powers to the Commissioner of Monopolies and Prices and the Minister for Finance (though it does not expressly make reference to



inventions) and thus enables the government to have two forums through which an uncompetitive determination may be made, this potentially creates conflicts between two government departments and would certainly give a patent holder an opportunity to cause delay by challenging an order on jurisdiction, competence and forum grounds.

Second, Section 80.1(B) provides an exception to the general provisions of Section 80, in that it shall not be a requirement for the patent holder, his licensee or interested party to be compensated upon a government-use order being issued. This may be contrary to the right to property conferred upon persons by the Kenya Constitution even though it is otherwise TRIPs-compliant.<sup>74</sup>

Third, it is not clear whether an application for government use must be made first by another person so that the Minister can issue a government-use order. The confusion results from the fact that the Act does not explicitly address this point but the subsidiary regulations do. Regulation 43 of the Industrial Property Regulations, 2002,<sup>75</sup> provides a clarification of the procedure to be followed in the issuance of a government-use order, in the shape of a form requesting the Minister to act. This implies that the Minister cannot, of his own motivation, issue a government-use order. However, some of the grounds established for issuance of a government-use order in the Act can only be determined by the government itself (such as security) or, at times, by the Minister issuing the order. Given that subsidiary regulations may not overrule a parent Act in its substance, that the Act seems to require an allowance for independent action by the Minister and usual interpretations of governmental use, the most reasonable interpretation would appear to be that the issuance of a government-use order may be initiated by private individuals or on the motivation of the Minister.

The fourth example relates to the third and is partly a question of ambiguity and partly one of a potentially “TRIPs plus” requirement. This is the fact that Section 80 requires that an applicant for a government-use order must first have “*unsuccessfully sought a contractual licence...*”. The ambiguous element of this Section is that which is related to the third example, above, as the language raises the question as to whether the Minister himself would have to submit a request for a voluntary licence before issuing a government-use order of his own volition. The TRIPs plus element is that even where public interest measures necessitate the Minister to issue a government-use order (except for national emergency or other extreme urgency), the Minister is required to apply for a voluntary licence. This requirement is clearly above and beyond the minimum standards required of Kenya by TRIPs Article 31(b) in relation to public non-commercial use under compulsory licences.

Experience with the implementation of provisions relating to government-use orders is almost as non-existent as that relating to compulsory licences. As mentioned earlier, one

of the local generic manufacturers, Cosmos Pharmaceuticals Ltd., made an application in August 2003 for government use. The genesis of the application is that Cosmos Ltd. was awarded a tender by the Ministry of Health in July 2003 to supply generic ARVs, which they cannot legally do without receiving either: a voluntary licence from the patent holder;<sup>76</sup> a compulsory licence; or, a government-use order. At the time of writing, it is understood that the Minister is considering the application and it is not known whether or when the order will be made.<sup>77</sup> The tender award already granted to Cosmos risks being cancelled by the Ministry of Health for failure to supply ARVs within the stipulated contractual period. Thus the government-use provision remains to be tested and clarifications on issues arising from the provisions are yet to be made.

### 3.6 Serious Health Hazard Exception

- Potentially very broad discretionary exclusion
- Allows for local manufacture of specific products that could supply both domestic and export markets

The 2001 Act, in its provisions regarding the meaning of “invention”, includes an innovative public health safeguard that exploits a range of potential TRIPs flexibilities. Section 21.3(e) provides that:

The following shall not be regarded as inventions and shall be excluded from patent protection –  
(e) public health-related methods of use or uses of any molecule or other substance whatsoever used for the prevention or treatment of any disease which the Minister responsible for matters relating to health may designate as a serious health hazard or as a life-threatening disease.

This is a potentially extremely broad provision allowing the Minister for Health to exclude any pharmaceutical product, or its active ingredients, from patentability, thereby obviating the need for more time-consuming bureaucratic processes, such as licences and orders, to access such a product.

The first, and perhaps least important aspect of TRIPs that Section 21.3(e) exploits is the fact that TRIPs does not explicitly provide for any definition of “invention”<sup>78</sup>, creating an argument that countries are free to define the term in any way they feel appropriate. The second form of flexibility that this clause exploits is the safeguard provisions of Articles 7 and 8 of TRIPs. Under Article 7 of TRIPs, it could be argued that Section 21.3(e) is designed to fulfil TRIPs’ objectives of implementing intellectual property rights “in a manner conducive to social and economic welfare, and to a balance of rights and obligations”. Under Article 8, Section 21.3(e) obviously constitutes a provision designed



to “protect public health” and thus fulfils the principles of TRIPs. Admittedly, in the latter case, Section 21.3(e) runs into the controversy regarding the meaning of “provided that such measures are consistent with the provisions of this Agreement”. However, regardless of the meaning of the text of Article 8, Section 21.3(e) could be seen as consistent with the provisions of TRIPs on the basis that it fulfils the requirements of one or more of Article 27.1, 27.3(a) and 27.2.

The health hazard exception may be subject to challenge under Article 27.1 of the TRIPs Agreement pursuant to an argument that the provision discriminates against a field of technology, namely pharmaceutical products. However, the focus of the health hazard exception is on public health, making it a provision that discriminates on the basis of a problem area rather than a technical field, and thus the exception may be deemed TRIPs compatible.<sup>79</sup>

The health hazard exception may also be justifiable in terms of Article 27.3(a), which provides that “[m]embers may also exclude from patentability...therapeutic...methods for the treatment of humans...”<sup>80</sup> There may, however, be some debate as to whether the public health use of a molecule or substance would be a “therapeutic method” within the understanding of Article 27.3(a),<sup>81</sup> particularly as such an interpretation would create a potentially very broad exception essentially allowing for all pharmaceuticals to be deemed non-patentable.

The final, and perhaps most important TRIPs flexibility exploited by Section 21.3(e) is the right, established by Article 27.2, of States to make exclusions from patentability “to protect human...health”. There is no discrimination between public and private or commercial and non-profit uses in this Article, provided that the basic purpose fits the stated criteria. The reference to “serious health hazard or...life threatening disease” clearly tracks this right and the fact that the invocation of Section 21.3(e) is dependent upon the executive discretion of the Minister fulfils Article 27.2’s requirement that such exclusions not be “made merely because the exploitation is prohibited by their law”.

Section 21.3(e) has not, as yet, been invoked by the Minister for Health; neither has it been publicly discussed as an option to address any access to medicines issue. However, as a means to authorize the local manufacture of any particular product it remains extremely potent. It may also be applied to APIs and related products and could thus have further significance for the capacity and options of local industry in that regard. It should also be noted that the invocation of Section 21.3(e) could potentially allow for manufacture aimed at both local and foreign markets, as TRIPs Article 27.2 is not subject to Article 31(f)’s limitation to supply of the domestic market.

### 3.7 Drug Registration and Regulation of Pharmaceutical Manufacturers

The Pharmacy and Poisons Act<sup>82</sup> makes provision for the control of the profession of pharmacy and trade in drugs and poisons. It is the relevant law for drug registration and regulation of pharmaceutical manufacturers. This Act came into force in 1957,<sup>83</sup> and has subsequently been amended on several occasions, the last comprehensive amendment having been made in 2002.<sup>84</sup> The Act establishes a Pharmacy and Poisons Board (PPB) whose functions include, *inter alia*, overseeing the drug registration process and licensing of pharmaceutical manufacturers in Kenya. With regard to drug registration,<sup>85</sup> the issue that has been of concern is the speed and procedure for registration of essential medicines, particularly ARVs. For example, even with the informal declaration of HIV/ AIDS as a national disaster, the Pharmacy and Poisons Board has not established credible fast-track procedures and guidelines for registration of generic ARVs. The rules prescribed with regard to drug registration are so inflexible that in emergency health situations in Kenya, essential medicines available abroad may not quickly be used. An example of this inflexibility lies in Rule (1) of the Pharmacy and Poisons (Registration of Drugs) Rules. This rule makes it mandatory for the Board, before registering a new drug for which the research work to establish its efficacy, safety and quality has been conducted abroad, to require an investigation of the pharmaceutical, pharmacological and other aspects of the drug, including clinical trials to be conducted locally.<sup>86</sup> With the recent outbreak of new diseases such as SARS and threats of bioterrorism, the implementation of this rule would not assist in meeting urgent objectives. The mandatory provision in this rule stifles the flexibility granted to the Board in executing the rule.<sup>87</sup> Besides, it is not known when these rules were last put into practice.

The slow speed of the registration process affects access to medicines in two ways. First, the lack of registration restricts access to generics in respect of off-patent medicines. Strictly speaking, this is not an intellectual property law issue but has some relevance to the overall strategy of improving access in the context of the use of the Bolar exception. If the registration process is very slow, much of the utility of the early working exception is negated, as a product still cannot be introduced immediately upon the expiry of the patent term. Secondly, slow registration procedures limit the possibility of using compulsory licences. A generic manufacturer would not be in a position to apply for a compulsory licence if he does not have a registered product to put on the market. The same problem may also apply to government use.<sup>88</sup>

### 3.8 Regional Frameworks

The most obvious of Kenya's intellectual property-related regional obligations is its



membership of the African Regional Intellectual Property Office (ARIPO). ARIPO serves 15 Anglophone African countries and provides a centralised service for patent applicants. ARIPO does grant patents that may be applicable in all of its member countries, however, each member country has a right to reject the application as regards its own jurisdiction, provided that such rejection is communicated to ARIPO within six months of the member country being notified of the application.<sup>89</sup> As a consequence, the exact nature of ARIPO's standards in the granting of patents, whether meeting or exceeding TRIPs standards, is not relevant to the patent standard in Kenya, TRIPs complaint or otherwise, as Kenya is free to reject any patent application approved by ARIPO.<sup>90</sup>

In addition, Kenya is a signatory to a number of bilateral and multilateral trade agreements. Key amongst these are the Treaty for the Establishment of the East African Community<sup>91</sup>, that Treaty's Customs Protocol, and the Common Market for Eastern and Southern Africa (COMESA)<sup>92</sup>. None of these trade agreements have 'TRIPs plus' measures. However, these agreements may impact the cost of medicines through non-intellectual property related measures. Negotiations to establish a customs union within the COMESA members are ongoing. The customs agreement is, however, not due to enter into force until 2008 and it is not known whether this will have 'TRIPs plus' provisions or whether the tariff reduction modalities will lead to increase of prices of essential medicines like the Customs Protocol. The key concern regarding the tariff reduction modalities is that Article 11 of the Protocol will require the imposition of tariffs that, in the case of Kenya, will have the effect of increasing current tariff levels for particular products, including finished pharmaceutical products, as discussed in section 2.1 above.

Finally, there are reports that Kenya and South Africa are negotiating a Free Trade Area Agreement (FTAA).<sup>93</sup> However, details on the FTAA are scarce, as the negotiations are said to be at an early stage and thus it is not known whether the FTAA will contain 'TRIPs plus' measures, TRIPs flexibilities or even any provisions relating to intellectual property rights.

### 3.9 Technical Assistance

The inclusion of public health flexibilities in the IP Act 2001 is at least partially the result of NGO technical assistance and lobbying. At the time the IP Act 2001 was enacted, technical assistance was mainly received from the World Intellectual Property Organization (WIPO) and from the WTO. The nature of the technical assistance was, however, relatively limited, being restricted to the provision of model draft legislation and some general financial and infrastructural assistance. However, further technical assistance was also provided from leading NGOs, including the KCAEM, through review of various draft IP Bills that were published prior to the IP Act 2001 and, as noted earlier,

through a report highlighting desirable public health safeguards. Many of those safeguards were adopted in Parliament and included in the IP Act 2001.<sup>94</sup>

Notwithstanding the adoption of favourable legislation, technical assistance is required in a number of key areas. Primarily this involves the very broad question of the implementation of the IP Act 2001 to take advantage of the TRIPs flexibilities. Whereas Kenya has a fairly comprehensive and flexible legislation that would potentially address public health needs, the law, since enactment, has not been utilized, with the exception of the provisions relating to parallel importation. Given that similar provisions in the 1989 Act, such as government-use orders and compulsory licences, went unused for some 10 years, it would seem that the relatively recent enactment of the 2001 Act is not the primary reason for this under-utilization. Several examples highlight different aspects of this point. First, the mechanisms required to use some of the flexibilities, particularly compulsory licences, were not put in place in a timely manner, as required by the Act. The establishment of the Industrial Property Tribunal in early 2004 is the most obvious case in this regard. Similarly, the KIPI Board was also not constituted until early 2004, despite its theoretically vital administrative and oversight role. Second, the failure to exploit some of the available flexibilities appears to be the result of a lack of awareness of the existence and nature of the options, both among potential users and within KIPI and the MoTI themselves. These situations highlight the need for a thorough review of what is required to properly implement the Act, in both administrative and technical terms. They also suggest that some consideration be given to means by which MoTI and KIPI might develop clear policies, and perhaps related awareness and capacity-building programmes, regarding the use of flexibilities under the Act, in particular compulsory licences and government-use orders.

Finally, technical assistance may be valuable to develop the capacities of MoTI and KIPI to effectively review and amend the Act. As noted variously in this paper, a range of amendments are currently under consideration and it is important that these are not made to the detriment of existing flexibilities and safeguards but, rather, entrench and expand such measures wherever possible. This is particularly true with respect to the somewhat complex flexibilities of the WTO's August 30<sup>th</sup> Paragraph 6 Implementation Agreement.



# 4 Future access scenarios

## 4.1 Post-2005 impacts

- Expected to affect existing parallel importation, particularly of ARVs and raw materials – however, actual impacts unknown due to lack of information regarding patent and mailbox status in other countries
- Will affect access to any new products that are patented post-2005 and, possibly, some that have been the object of 'mailbox' applications between 1995 and 2005
- No formal assessment of impacts undertaken or currently planned
- Limited awareness or coordination among agencies and ministries

The expiry of grace periods in 2005 for countries that did not grant product patents for pharmaceuticals prior to the entry into force of TRIPs is expected to have varied impacts in Kenya, some foreseeable and others not. The main concern in the former category is as regards ARVs that have come onto the market, or that are the object of multiple patents for altered compositions or uses, between 1995 and the present time. As can be seen in Annex I hereto, several key ARVs will remain under patent in Kenya well beyond 2006<sup>95</sup> and it is assumed<sup>96</sup> that their manufacture will be similarly limited in key generic-producing countries, such as India. The current prices of first and second line ARV triple therapy, and the availability of fixed-dose combinations, are highly dependent on the parallel importation of generics and any increase in prices will undoubtedly mean that thousands of patients will have to interrupt their treatment and others will never have the opportunity to begin.<sup>97</sup> Although local generic manufacturers have begun to enter the anti-retroviral market, it is unlikely that they will be able to provide an affordable quality substitute for all of the drugs that are currently imported. This is partly a question of capacity and profitability but, perhaps more significantly, also a question of the availability of voluntary and compulsory licences or governmental-use orders for local generic production: something that is not yet clear. Licences and governmental-use orders may mitigate the impact of 2005 on finished products in terms of allowing local manufacturers to enter the market for particularly sensitive products, but these solutions alone will not solve the problem. Kenya faces the additional problem that it is also dependent on importation as a source of active, and often basic non-active, ingredients. If affordable sources of raw materials are not secured, this will obviously undermine any efforts to promote local generic manufacture. It is important to note that all of these possible impacts of 2005 are dependent on the intellectual property rights status of products in other countries: where there are no patents or mailbox applications, current practice may continue without any change after 2005. The main problem is that Kenyan institutions and authorities have not sought to collect the information necessary to assess what the future situation will be.<sup>98</sup>

The less foreseeable impact of the 2005 deadline relates to the possibility of new drug development. Some finished products and raw materials may not be the subject of mailbox applications in countries such as India and thus continue to be available from generic manufacturers in these countries. However, there can be little doubt that any new products for the treatment of key public health problems, such as malaria, TB or HIV/AIDS<sup>99</sup> will be the subject of patents in the key generic-producing countries and thus likely to be prohibitively expensive. Similarly, the increased prevalence of patents may inhibit the development of innovations such as fixed-dose combination drugs.<sup>100</sup>

The lack of specificity regarding the expected and potential impacts, if any, of the 2005 deadline on access to medicines in Kenya is largely the result of the fact that there has been no systematic survey or assessment. Most government ministries and agencies and most civil society organizations have only limited awareness of the issue. Those that are aware generally know little more than that it is an issue and believe that there is an urgent need for awareness raising, capacity building and substantive analysis. The intellectual property rights authorities believe that the issue is primarily one for the drug procurement authorities and the latter, where they have any knowledge at all, have only limited capacity and resources to consider it.

## 4.2 Current strategies for post 2005

- There are no current strategies in place, whether for the public or non-profit sectors, to respond to the 2005 deadline
- There is no current initiative seeking to develop such a strategy

As is noted variously in this paper, there are no strategies currently in place to respond to the 2005 expiry of the grace period for the granting of pharmaceutical product patents in key generic-producing countries. Neither is there any current initiative to develop such a strategy. In Kenya, this is overwhelmingly a problem relating to the situation in India, as the major source of imported generic drugs, in particular those affected by intellectual property rights. However, the situation in Pakistan and China (particularly with the latter's status as a new WTO member and thus not covered by grace periods such as the 2005 and 2006 deadlines) may also be important. There is some awareness of the situation in South Africa, due to political and economic proximity, but even this is limited. In addition, it may be useful for Kenya to explore options that it has not previously made use of, such as imports from South East Asia or Latin America, where it finds problems with its existing suppliers and is unable to address these locally.

The development of a viable strategy, even if, as now seems likely, it will be developed after 2005, will require several components. First, a review of the actual likely impacts of 2005: what products may be affected and in which countries? Second, are there acceptable alternative, unaffected, sources of supply for the products that are likely to be affected? Third,

where likely impacts are identified and alternative sources are not available or practical, how might the existing IP Act 2001 be used to address them? Fourth, where the existing IP Act 2001 might be inadequate to address the situation, how might Kenya incorporate the August 30<sup>th</sup> decision into its policy and legislation as an effective solution? Addressing all of these components requires specialized skills and at least minimal resources, things that are not readily available to the authorities, in particular KIPi and MoTI, at the present time. Therefore, the development of any comprehensive approach to the 2005 deadline is likely to be dependent upon the interest and will of donor agencies and countries. In the absence of such interest and will, the prevailing view is that 2005 will be dealt with in the same manner as similar situations have been dealt with in the past: something will happen and it will become a crisis, then we'll work out some way to deal with it.<sup>101</sup>

### 4.3 Related initiatives

Pharmaceutical manufacture includes all operations - purchasing of material, processing, production, packaging, quality control, release and storage of medicinal products and related control.<sup>102</sup> Kaplan et al. succinctly outline various factors as general preconditions for economically viable domestic pharmaceutical production.<sup>103</sup> They include a high ratio of domestic R&D to gross domestic product (GDP) since production in the pharmaceutical sector is technology driven; size of economy; income level in the domestic market; availability of reliable local infrastructure and amenities at competitive prices; policies that govern local production and their enforceability to ensure efficiency and reliability of the market; and the structure of tariff barriers in the pharmaceutical market.

Notwithstanding these barriers, there are a number of structural and policy measures which if undertaken would, to a certain extent, enable local producers to achieve sufficient economies of scale to be able to supply a country issuing a compulsory licence in a post-2005 scenario. The first of these, as discussed elsewhere, is the WHO prequalification system. Taken in the context of generic production, WHO prequalification is essential as it not only assures Good Manufacturing Practice (GMP) and quality pharmaceutical products but also, as of January 2005, access to programmes and markets governed by procurement rules imposed by international donors such as the Global Fund and the World Bank.

Within the country other steps need to be taken. These include fostering better and closer working relations between the local manufacturing industry and the Ministry of Health and other state actors such as national research institutions and public universities, as in the current environment effective interaction between these only seems to occur as a result of specific events, such as government drug tendering processes and free medical camps.<sup>104</sup> This would not only assist early addressing of technical and other issues affecting the pharmaceutical sector such as the ongoing debate on carrying out bioequivalence tests but also in a way contribute towards the improvement of R&D capacity, and mutual exchange of actionable knowledge.



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## 5 Conclusion

The conclusions provided here do not stand alone, they supplement and complement substantive points raised in the various sections of this paper. In the context of the supply of essential medicines in Kenya, two key points relating to the promotion of local manufacture, and thus improved stability and competitiveness in the market, should be considered:

- Local generic manufacturers should consider, and be assisted in, establishing long-term relationships with foreign generic manufacturers so that they can access better manufacturing technologies and skills;
- Efforts should be made to promote interest in WHO prequalification among local generic manufacturers and GMP should be more actively enforced.

In relation to existing law and practice regarding intellectual property rights and access to medicines in Kenya, a number of points, apart from those highlighted elsewhere in this text, stand out as ones that could usefully be addressed to increase the effectiveness of Kenya's current system.

First is the fact, noted elsewhere, that there is a major need for capacity-building activities relating to the implementation of flexibilities under existing legislation. Kenya, in common with a number of developing countries, has a history of well-drafted but redundant legislation due to lack of awareness and capacity among the public and the relevant authorities.

A second general issue is that of the pending review of Kenya's competition legislation. This review could usefully consider the interaction between general competition legislation and the Industrial Property Act and examine means of mutual reinforcement, particularly in the areas of mechanisms adjudicating on the anti-competitiveness, or otherwise, of particular activities and enforcement. Given that the review is being led by the Attorney General's Chambers and the Kenya Law Review Commission, neither of whom are familiar with intellectual property rights issues, some technical assistance or broadening of participation is clearly needed.

More specifically, at least three points could usefully be addressed. One is that the asymmetry in the treatment of imported vs. locally manufactured products should be corrected. Kenya's parallel importation provisions allow for the importation of a broad range of products under flexible conditions that do not usually require government

intervention. At the same time, local manufacturers have to accommodate a complex and uncertain bureaucratic process before they can obtain the compulsory licence or government-use order that is a prerequisite for local manufacture of the same products. This is a clear bias towards foreign generic manufacturers at the expense of local manufacturers. The means to ameliorate the situation would need to be considered in depth, as the aim would be to lower the levels of complexity facing local manufacturers to levels similar to those facing importers, rather than increasing the barriers facing importers and creating a generally more restrictive environment. One option might be to determine that government tenders, i.e. public non-commercial use, for pharmaceuticals (or other products) are assumed by implication to contain automatic government-use orders for their objects, as is effectively the case in some other developed country jurisdictions. Such a measure might not even require a statutory amendment, as the authority could be delegated to all ministers through a Gazette notice by the Minister for Trade and Industry and, perhaps, regulatory provisions pursuant to Section 80.

A second specific point is as regards current practice on voluntary licences. The first element of this is that the existing statutory requirements on licence contract provisions should be reviewed with broad stakeholder participation to determine whether they are a help or a hindrance to technology transfer. The second element is that the current lack of enforcement of voluntary licence provisions needs to be considered. This is particularly important from the perspective of the connection between voluntary licences and mechanisms such as compulsory licences and government-use orders: if the risk of these latter measures was perceived as more imminent and real, as is the case in Brazil, then there might be more pressure for patent holders to grant voluntary licences.

A third specific point arises from the first general point made above. This is that compulsory licences and government-use order provisions are currently ineffective due to a lack of awareness and capacity among both government authorities and agencies and potential applicants. In addition, the fact that this lack of awareness and capacity has been perceived, in the one example of an application for a government-use order, to, *inter alia*, encourage a lack of transparency and accountability on the part of the decision-making authorities does not promote the further use of such mechanisms. This point could probably be effectively addressed by the elaboration of a clear policy and some outreach activities by the relevant authorities. However, even these measures might require some level of technical and financial assistance.

A further aspect of the question of awareness and capacity has only been addressed indirectly in this study and relates to the application of basic standards in the granting of patents. If KIPi were to apply relatively strict interpretations of novelty and non-obviousness, it could limit the granting of secondary patents, such as new formulations, and ensure the maximum availability of products at the expiry of patents on basic

substances. Such an approach would not require any legislative action and would ensure that more complex and burdensome safeguard measures, such as compulsory licences and governmental-use orders, would only need to be applied in a narrower range of cases.

In the context of the registration of medicines and the regulation of the pharmaceutical industry, the needs are relatively simple, but extremely wide-ranging. The first need is that the Pharmacy and Poisons Act should be comprehensively reviewed with a particular focus on current and future needs and past shortcomings. In this context, the roles played by the PPB and the National Drug Quality Control Laboratory (NDQCL) should be clearly spelt out to avoid overlap of mandates and to ensure their independence in the execution of their functions. It would be highly desirable if the review and reform measures addressed long delays in registering medicines, including those caused by requiring local clinical trials. In addition, it would be highly desirable to provide for expedited approval of medicines already approved by the WHO Prequalification Project, including, in particular, fixed-dose combinations.

Finally, regarding general policy issues, and the 2005 deadline and August 30<sup>th</sup> decision in particular, the major need is for an immediate assessment of the likely impacts. This will initially involve the gathering and analysis of information from major generic-producing countries, such as India, but in the event that this analysis highlights potential problems, the review should also allow for the development of effective strategies to accommodate any expected changes. The role of international bodies and donors may be particularly significant in this regard due to their ability to access expertise in a wide range of countries and rapidly compile information through their existing networks. For a country such as Kenya to accurately assess the situation in even its current generic-supplying partner countries, including China, Brazil, India, Pakistan and South Africa to name but a few, is an almost impossible task. In addition, it may well be a redundant one as the same situation affects a number of other developing countries with limited manufacturing capacity, both within and beyond Africa, and thus international cooperation would appear to be the most effective approach.



# Annex I

## Patent Status of Some Essential Drugs in Kenya and Patent Status of ARVs in Kenya, June 2002<sup>a</sup>

### PATENT STATUS OF SOME ESSENTIAL DRUGS

Patents granted either by KIPO (Kenya) or ARIPO (AP)

\*All Kenya patents (KE) registered before 1990 have effect for 20 years, calculated from the filing date in the UK

Generic name	Kenya Patent number	Protection of:	Foreign priority date	Filing date	Kenya Expiry date	Patent status in Kenya
acyclovir	KE3002	basic substance	02/09/74	02/09/75 (UK) 13/11/79 (KE)	02/09/95	expired
	KE3561	new formulation and use	18/07/80	17/07/81 (UK) 18/09/85 (KE)	17/07/01	expired
	AP160	new composition and use	15/08/87	10/08/88	10/08/08	in force
azithromycin	AP44	new form	09/07/87	15/06/88	15/06/08	in force
	AP566	new dosage form	29/04/94	06/04/95	06/04/15	in force
ceftriaxone	KE3268	substance patent	30/05/78	29/05/79 (UK) 29/03/83 (KE)	30/05/99	expired
	KE3724	new process	28/03/80	25/03/81 (UK) 30/04/87 (KE)	25/03/01	expired
ciprofloxacin	KE3545	basic substance	03/09/80	21/08/81 (UK) 19/06/85 (KE)	21/08/01	expired
	KE3875	new composition	17/09/83	04/09/84 (UK) 20/04/89 (KE)	04/09/04	in force
fluconazole	KE3771	basic substance	06/06/81	22/04/82 (UK) 29/09/87 (KE)	22/04/02	expired
	KE3867	new process	25/05/83	16/02/84 (UK)	16/02/04	expired

a The information presented in this Annex was kindly provided by the Kenya office of Médecins sans Frontières (Belgium).

## PATENT STATUS OF ARVs IN KENYA

Generic name	Kenya Patent number	Protection of:	Foreign priority date	Filing date	Kenya Expiry date	Patent status in Kenya
abacavir	AP196	basic substance	22/12/89	21/12/90	21/12/10	in force
AZT+3TC	AP652	new composition	30/03/95	28/03/97	28/03/14	in force
didanosine	no patent					
efavirenz	no patent					
indinavir	no patent					
lamivudine	AP136	basic substance	08/02/89	08/02/90	08/02/10	in force
	AP182	new form	02/05/90	02/05/91	02/05/11	in force
	AP321	new process and use	01/08/91	31/07/92	31/07/12	in force
nelfinavir	AP600	basic substance	07/10/93	07/10/94	07/10/14	in force
nevirapine	AP189	basic substance	28/06/89	28/06/90	28/06/10	in force
	AP179	new form	17/11/89	16/11/90	16/11/10	in force
ritonavir	no patent					
saquinavir	no patent					
stavudine	no patent					
zalcitabine	no patent					
zidovudine	AP11	composition and use	16/03/85	14/03/86	14/03/06	in force

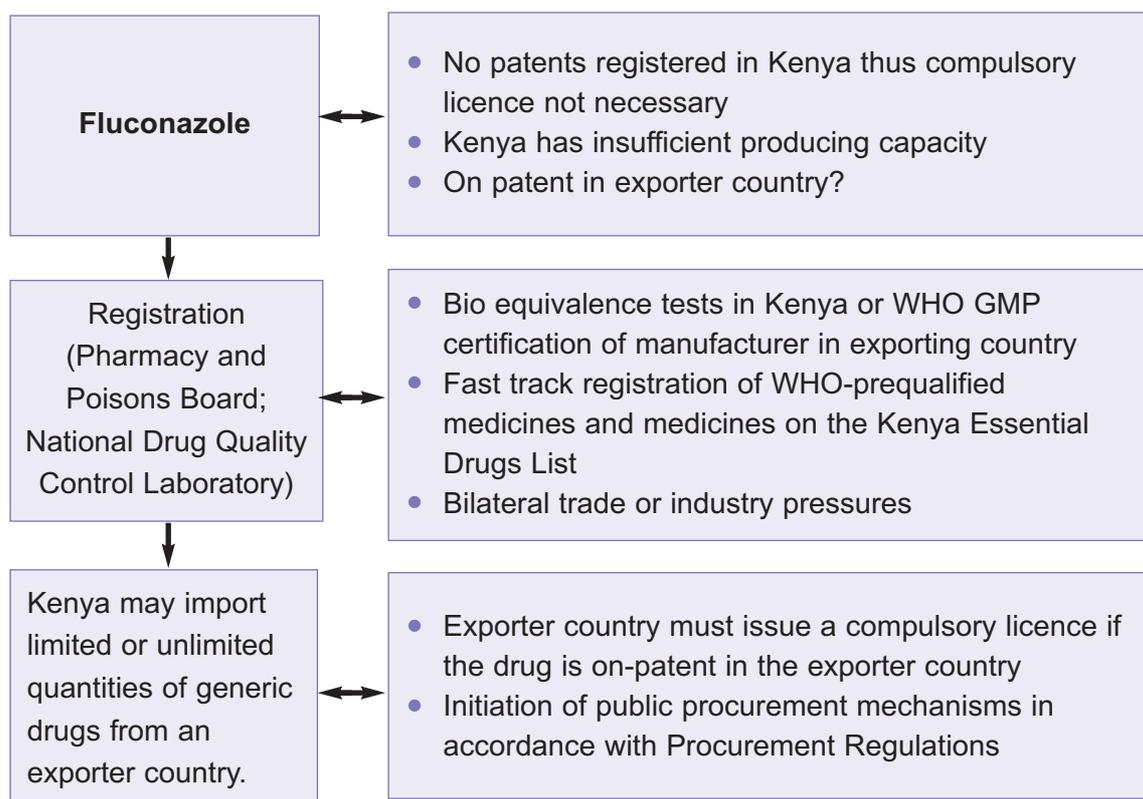


# Annex II

## Decision tree 1- Importation of a non-patented drug in Kenya in a post-2005 scenario

### FLUCONAZOLE<sup>b</sup>

Two patents with respect to fluconazole were registered in Kenya but have since expired. The first was for protection of the basic substance, while the second was to protect new processes, which expired on 22<sup>nd</sup> April 2002 and 16<sup>th</sup> February 2004 respectively. Both patents have not been renewed and the drug is therefore not patented in Kenya.



Note: Whereas it is important for the patent status of drugs in Kenya to be known in the analysis of a post-2005 importation scenario, establishing the patent status of the drug in potential exporter countries is critical.

<sup>b</sup> Fluconazole is the generic version of Pfizer's Diflucan. It is an anti-fungal drug used, *inter alia*, to treat cryptococcal meningitis, one of the most severe opportunistic infections associated with HIV/AIDS in Kenya. There have been occasions where there has been a low supply of fluconazole in the health sector in Kenya. Fluconazole, in its basic substance, was first patented prior to 1995 and is thus unlikely to be affected by the 2005 deadline. It is used here as an example illustrating the on- and off-patent options for importation.

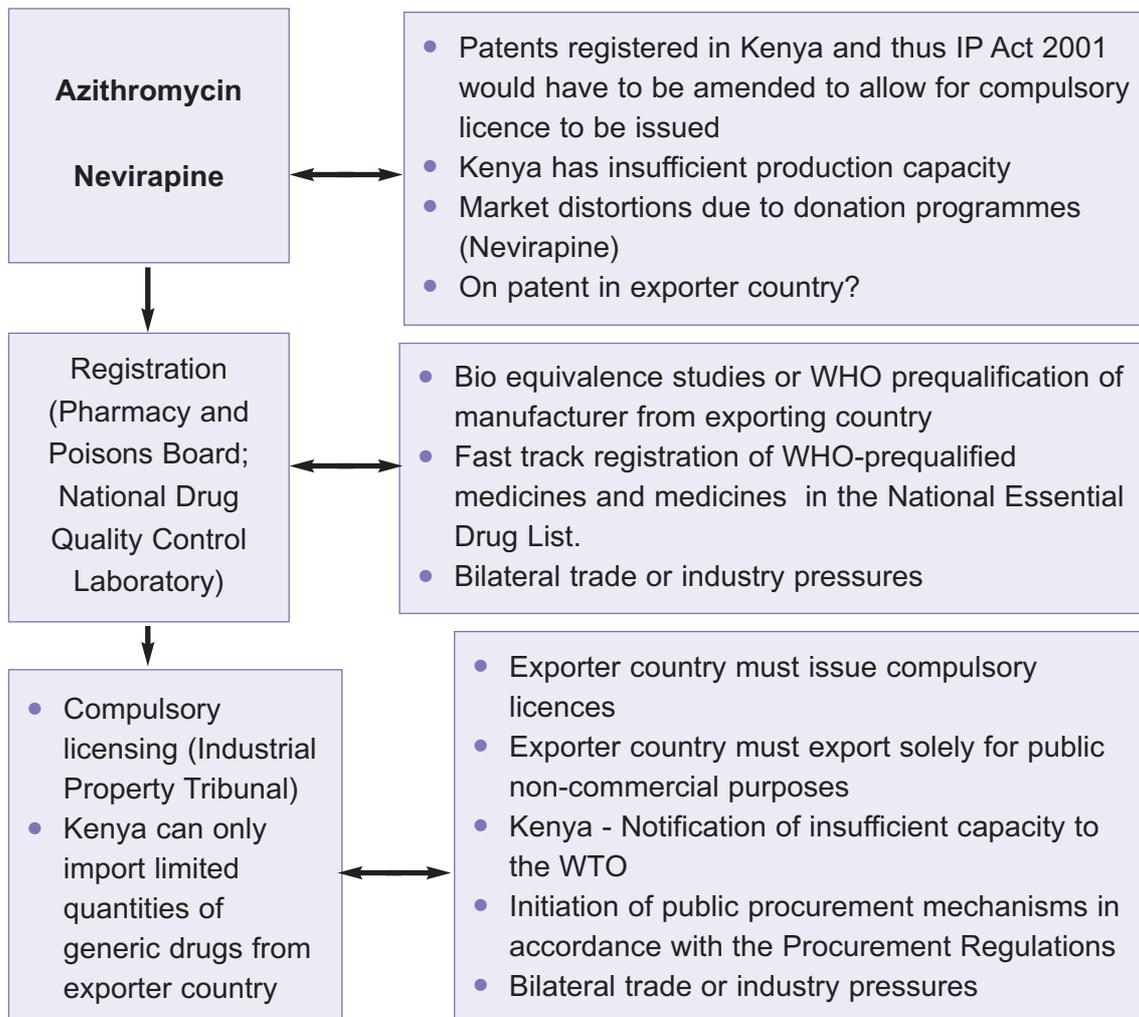


# Annex III

## Decision tree 2- Importation of a patented drug in Kenya in a post-2005 scenario

### Azithromycin<sup>c</sup> and Nevirapine<sup>d</sup>

Two patents with respect to azithromycin are currently in force in Kenya: one on new form that is in force until 15<sup>th</sup> June 2008, and another with respect to new dosage form that is in force until 6<sup>th</sup> April 2015. The patent on Nevirapine, which is with regard to basic substance, is in force in Kenya until 28<sup>th</sup> June 2010.



<sup>c</sup> Azithromycin is the antibiotic generic version of Pfizer's Zithromax. It is used to treat respiratory infections such as tonsillitis, a common childhood infection in Kenya.

<sup>d</sup> Nevirapine is the generic version of Boehringer Ingelheim's Viramune, a non-nucleoside analogue reverse transcriptase inhibitor. The drug is used in the prevention of mother to child transmission (PMTCT) of HIV and in first line ARV triple therapy.



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## Notes

1 Institute of Economic Affairs (2002) at p. x.

2 Id.

3 The main exception to this is medicines for the treatment of tuberculosis, which are provided free of charge but which are also frequently unavailable.

4 The Ministry of Health was previously split between the Minister for Health and the Minister for Medical Services, whereas these positions are now unified with the latter having been abolished.

5 McNeil Jr. (2000).

6 Parliament of the Republic of Kenya (2000).

7 Mission hospitals are mainly run by faith-based organizations and churches while non-governmental organizations offering health services include MSF, Norwegian People's Aid and Pharmaciens sans Frontières to name a few.

8 KEMSA is a corporate body established under the Public Corporations Act. While, like other corporate bodies incorporated by Acts of Parliament in Kenya, it is required to be independent from government influence, KEMSA's functions over the last years have been overshadowed by the Ministry of Health. This is partly because while KEMSA was incorporated to act as the sole procuring agent of the Ministry, the Ministry has at times made procurements on its own or by employing procurement agents, Crown Agents in this case. However, since late 2003 KEMSA has been undergoing reorganization and it is hoped that by June 2004, it will be the sole procurement and distribution agency of essential medicines and other essential surgical equipment for all public hospitals in Kenya.

9 Since June 2002 the Ministry of Health has issued at least two tenders for essential drugs. Whereas details of the tender awardees were not disclosed, it is understood that local pharmaceutical manufacturers were granted a large share of the tenders. Personal communication to the authors by Dr. W. O. Wanyanga, Manager Regulatory Affairs, Cosmos Limited (7th April 2004).

10 Personal communication to the authors by Dr. W. O Wanyanga, Manager Regulatory Affairs, Cosmos Limited (25th May 2004).

11 The inclusion of European generic manufacturers in this case stems from the fact that whereas MEDS procures over 98% of its essential medicines from local sources, that is from local generic manufacturers and local distributors for branded drugs, when it comes to imports (excluding anti-retrovirals, or ARVs), MEDS usually procures these through the International Dispensary Association (IDA), a not-for-profit institution based in the Netherlands, which in turn purchases generics from European and developing country manufacturers on MEDS' behalf. With regard to generic ARVs, MEDS procures these from India. Personal communication to the authors by Ms. Alice Micheni, Purchasing Manager, MEDS (25th May 2004).

12 MEDS is a non-profit making organization. It was formed in 1986 by the Kenya Episcopal Conference (KEC) and Christian Health Association of Kenya (CHAK) with

the objective to inter alia provide a reliable supply of good-quality essential drugs and medical supplies at affordable prices. Over time, MEDS has also become a key supplier of essential medicines to a number of NGOs (currently, 154 NGOs) and at times procures for the Ministry of Health but on an *ad hoc* basis. MEDS' sales to the Ministry of Health account for just over 2% of its annual turnover.

13 Wanyanga (2004).

14 *Supra* note 1. For the last decade Kenya's economy has been going through a very difficult period. It has had five years of constant decline and in 2000, the economy actually registered its worst performance since 1963 at -0.3% growth.

15 *Id.*

16 See Lall (2003).

17 There are 33 companies in Kenya registered as pharmaceutical manufacturers with the Pharmacy and Poisons Board.

18 See Okwemba (2004) and personal communication to the authors by Dr. W. O. Wanyanga, Manager Regulatory Affairs, Cosmos Limited (25th May 2004).

19 For example, Cosmos Limited manufactures over 80% of the medicines on the Kenya Essential Drug List. Personal communication to the authors by Dr. W. O. Wanyanga, Manager Regulatory Affairs, Cosmos Limited (25th May 2004).

20 For example, the age of Cosmos Limited's production facilities, which are said to be one of the most efficient and "latest", range from 10 to 25 years. Besides, their relationships with foreign pharmaceutical manufacturers, if any, are purely contractual and *ad hoc*, based mainly on purchase and supply of raw materials and equipment. None of the local manufacturers is currently known to be investigating technology transfer or long-term partnerships with foreign generic manufacturers. Personal communication to the authors by Dr. W. O. Wanyanga, Manager Regulatory Affairs, Cosmos Limited (25th May 2004).

21 The cost of electricity for industrial consumers in Kenya is about four times that in Egypt and South Africa, and almost double that in Uganda. See [www.allafrica.com](http://www.allafrica.com), last accessed on 20th April 2004.

22 Lack of a market is dependent on the price of the medicines and their affordability, cost of production, the actual number of patients, and competition. In the case of ARVs, the cause of 'lack of market' in Kenya is attributed to all these factors, each to a certain degree.

23 See <http://mednet3.who.int/prequal/>.

24 This Protocol was signed on 2nd March 2004 by the presidents of Kenya, Uganda and Tanzania under the auspices of the Treaty establishing the East African Community. Also see Kimani (2004).

25 Every importer, whether of medicines or not, is required by Kenyan law to pay either KShs 5,000/- (equivalent to US\$ 66) or 2.75% of the import value, whichever is the higher, for Import Declaration Forms prior to importation. Medicines are zero rated for the purposes of value added tax, meaning that no tax is payable.

26 For example, the Kenyan public sector has depended on donations for the provision of nevirapine for the treatment of mother to child transmission of HIV/AIDS. The long-term sustainability of this programme is unclear and alternative cost-effective sources have only been superficially explored.

27 Similar to many common law countries, Kenya recognises a division between industrial property (e.g. patents, petty patents, trademarks) and copyright. KIPi is responsible for industrial property, under the auspices of the Ministry of Trade, while the Attorney General's Chambers, containing the Office of the Registrar General, is responsible for copyright.

28 Kenya was a founding member of the WTO in 1995, having previously been a party to the General Agreement on Tariffs and Trade (GATT 1947).

29 While a number of interest groups submitted position papers on other industrial property-related issues, access to medicines came to dominate debate and that is what is considered here.

30 In this case, understood so as to include local, national and international NGOs, private individuals and other institutions such as mission hospitals.

31 The KCAEM membership included international NGOs such as Médecins sans Frontières, Health Action International and ActionAid Kenya, a number of Kenyan NGOs such as Women Fighting AIDS in Kenya (WOFAK) and a number of individuals from various backgrounds and professions.

32 Lettington and Musungu (2000).

33 Personal communication to the authors from Prof. Norah Olembo, Director KIPO/KIPi (2000).

34 Personal communication to the authors from Hon. Nicholas Biwott, Minister for Trade and Industry (2001).

35 Kenya Gazette Supplement No.60, 3rd August 2001.

36 See Section 1, IP Act 2001 and Legal Notice No. 53 of 2002 of 12th April 2002. This effectively meant that Kenya was some 18 months late in fulfilling its obligations but this raised no protest at the WTO. The delay prior to the passage of the Act was due to problems with the Parliamentary calendar, and after the passage of the Act, there were delays in the preparation of implementing regulations.

37 Musungu (2002).

38 Chapter 509, Laws of Kenya (1989, repealed by the 2001 Act)

39 Also see IP/C/M/40. While commenting on the question of Kenya's review at the Council for TRIPs, the chairman of the Council noted "Kenya... had now provided responses to all questions posed... and all these responses had been circulated to Members prior to the meeting." He proposed that the reviews of the legislation of Kenya... "be deleted from the agenda, it being understood that any delegation should feel free to revert to any issue stemming from these reviews at any time." The ambiguity of this closing language is the basis of stating that the legislation is presumed to be generally compliant, rather than definitively stating that it is compliant.

40 Section 80, IP Act 2001.

41 Chapter 504, Laws of Kenya (1989).

42 Personal communications to the authors from Dr. Peter Njoroge, Commissioner of Monopolies and Prices (April 2004) and Mr. Spencer Muthoka, Acting KIPi Managing Director (May 2004).

43 The market control picture for ARVs was similar to that globally, while some 60% of the general brand name pharmaceutical market was estimated to be controlled by just one company.

44 The fact that parallel importation did not depend upon any bureaucratic procedure or discretionary decision-making was perceived as a major element of its potential to provide immediate tangible results.

45 The Parliamentary Health Committee was particularly supportive on this point.

46 At the time, the case of fluconazole, marketed by Pfizer as Diflucan, was of particular concern. In Kenya, Diflucan sold for the equivalent of approximately US\$18 per dose, while in Thailand the branded product was selling for the equivalent of approximately US\$7 and a generic version for the equivalent of approximately 20 US cents. Parallel importation based on branded products would, thus, have represented a considerable improvement in prices but only the importation of generics would have potentially provided access to the drug for the majority of the Kenyan population. While most attention has been given to FPPs, parallel importation provisions could equally be applied to APIs and related products.

47 Lettington and Musungu at 20 (2000).

48 See Correa at 78 – 79 (2000).

49 TRIPs Article 6, “Exhaustion”, does not provide any detail regarding the concept of the exhaustion of rights and simply states that, “[f]or the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights”. The details of the concept exist, in varying forms, in national legislation and case law and are a subject of academic discourse but do not constitute any uniform, legally binding, standard. *Supra* note 48 at 73 – 74.

50 The majority of Members of Parliament were unaware of the intricacies of patent law and, thus, did not realize that the text they agreed on potentially represented a concept different from that proposed by either side in the debate.

51 There was a delay of 10 months from the approval of the Act and assent by the President until its entry into force due to delays in the preparation of implementing regulations under the Act.

52 Those relating to the media had been the subject of particularly heated debate.

53 In particular, the Chairman of the Parliamentary Health Committee and the Opposition Chief Whip.

54 Practice in Kenya is that the parent Ministry of any Act should be the sponsor of any amendment while, in rare circumstances, the Attorney General’s Chambers may

propose amendments to correct typographical errors. Stories in the local and international press tentatively linked the amendment to a law firm that, *inter alia*, represented a multinational pharmaceutical company, but neither this nor any other origin have ever been confirmed.

55 Section 69 (chapeau), IP Act 2001.

56 It should be noted that some aspects of this problem may persist even with the new statutory provisions on exhaustion of rights. Where products are locally manufactured by a subsidiary, where they are only distributed (as opposed to purchased and sold on) by an agent or where a trademark is used by either a subsidiary or an agent, there should be a licensing agreement to that effect and this agreement should be registered with, and approved by, KIPi. Given that very few agreements have followed this process, it would appear that a substantial amount of commercial activity in Kenya is technically in violation of the voluntary licence provisions of the IP Act 2001.

57 Personal communication to the authors, Prof. Norah Olemba, KIPi/KIPO Managing Director (2000).

58 Confidential personal communication to the authors, representative of a Kenya generic manufacturer, identity withheld (2000). The manufacturer in question raised the concern that, if they were to make a request, this might be seen purely as a prelude to an application for a compulsory licence, and thus provocative. The concern was based on the fact that brand name manufacturers, and associated diplomatic missions, were perceived as able to exert considerable pressure on the relevant Kenyan authorities, in particular MoH and MoTI, which in turn could exert pressure on the local manufacturers through bureaucratic restrictions and requirements. It remains to be seen whether this situation has changed with the transfer of political regime in 2002, although the current environment appears more positive.

59 The main example regarding which information is available is that of Cosmos Pharmaceuticals Ltd., who requested a voluntary licence from a major multinational pharmaceutical company for rights to locally manufacture and distribute an individual product in Kenya. Initially, there was no response to the request and, after a period of some months, it was responded to with what Cosmos regarded as unacceptable conditions. Personal communication to the authors, Dr. W. O. Wanyanga, Cosmos Pharmaceuticals (2000).

60 See note 59.

61 A representative of the multinational company to which Cosmos made its request, see note 59, unofficially stated this as their main reason for not cooperating. Confidential personal communication to the author, identity withheld (2000).

62 As established by Section 113.1 of the 2001 Act. The Tribunal consists of: a Chairman who must be a lawyer who has been, or is qualified to be, a judge of the High Court; two lawyers with at least seven years of practice each; and, two other members with industrial, scientific or technological expertise. All five members are appointed by the Minister for Trade and Industry.

63 As noted later in this section, the case of FDCs may not actually be functional under Section 73 due to the fact that FDCs themselves are often not patented. The example is used here as a simple means of demonstrating the technical aspects of the relationship between “nested” inventions in the context of pharmaceutical products. However, during the preparation of this study several patents for FDCs have been issued and the situation appears to be shifting.

64 *Force majeure* refers to events that are beyond the reasonable control of the patent holder and, usually, that are of limited duration.

65 The declaration was initially made as a “roadside” statement by President Moi and was only formally gazetted some months later.

66 The KCAEM and some of its member organizations considered this option but ultimately it has not been used. The main issue regarding this option has been that, even if products, particularly FPPs, are purchased and then distributed for free or at cost, such activities still potentially impact on the industry and commerce of market players in much the same way that there is concern upon the commercial and industrial impacts of brand name donations on the generic market. In addition, such an interpretation of Section 58.1 would render the utility of governmental use orders for public non-profit use somewhat moot and, therefore be somewhat illogical. However, the invocation of Section 58.1 might still have potential in the event of an aggressive policy interpretation by KIPi. It should also be noted that arguments for the use of Section 58.1 are far weaker when applied to APIs and raw materials than when applied to FPPs.

67 This is similar to the situation with requests for voluntary licences, see section 3.3 above and, in particular, notes 58 and 59.

68 Section 80.

69 *Musungu* at 26 (2002).

70 Section 80.1(A),

71 Section 80.1(B).

72 Section 80.2 explicitly states that the Minister may order the utilization of any process for the manufacture, sale or supply of any molecule or substance whatsoever. However, there seems to be a slight distinction on the limits of a government-use order between a product patent and a process patent such that an order for the importation of a product manufactured by a patent protected process cannot be made. While in its lay sense ‘importation’ may be seen to mean the act of bringing in goods from other countries, in legal terms and especially when considering the case for process patents it may be defined to include transfer of technology in line with Article 67 of the TRIPs Agreement.

73 Chapter 504, Laws of Kenya.

74 Section 75, The Constitution of Kenya (1992) (1987), as amended 1997. KIPi has stated its intention of amending this provision. Personal communication to the authors, Mr. John Muchai, KIPi Deputy Managing Director (Legal) (June 2002).

75 Legal Notice No. 50, Kenya Gazette Supplement No. 31 (Legislative Supplement No. 19) 12th April 2002.

76 The legal basis of the application for a government-use order is that Cosmos had already requested a voluntary licence and had not been granted this on reasonable terms. See note 59.

77 Information regarding the decision-making process and influencing factors is extremely scarce.

78 Although some might argue that the provisions of TRIPs Article 27.1 provide a de facto definition, the wildly varying definitions and interpretations of invention, particularly in terms of invention vs. discovery, around the world would suggest that this is not the case.

79 Although the references to “molecule or other substance” and “prevention or treatment” could be argued to constitute a thinly-veiled proxy for “pharmaceuticals”, thereby constituting discrimination against a technical field, a violation of TRIPs. The review and approval of the 2001 Act by the TRIPs Council would, however, suggest that this view has not been adopted.

80 The Oxford English Dictionary definition of “therapeutic” is “of or relating to the healing of disease”. The Concise Oxford Dictionary, Tenth Edition (OUP, 2001)

81 It is possible to argue a distinction between “use” and “method of use”: use being the actual use and the method of use being its specific means of delivery, dosage etc. In such a scenario, the use of a molecule might be patented but, should that patent expire, the use of the molecule could not be further restricted by the patenting of methods of use.

82 Chapter 244, Laws of Kenya.

83 Legal Notice Number 17 of 1956

84 Statute (Miscellaneous Amendment) Act No. 2 of 2002.

85 Rule 3, The Pharmacy and Poisons (Registration of Drugs) Rules. It is a legal requirement that any drug imported, manufactured for sale or sold in Kenya must be registered.

86 In practice, this rule is frequently violated and no trials are conducted due to a lack of capacity and resources.

87 Rules 9 (2 and 3). The Pharmacy and Poisons (Registration of Drugs) Rules. Rule 9.2 grants the Pharmacy and Poisons Board authority to dispense with investigations and clinical trials prior to registration, while Rule 9.3 grants the Pharmacy and Poisons Board discretion to register a drug where public interest so requires.

88 Musungu at 42 (2002).

89 This is in contrast to the mechanisms of the Organisation Africaine de la Propriété Intellectuelle (OAPI), which issues patents that are automatically valid in all of its member countries. Current OAPI member states include a number of Francophone West and Central African states.

90 However, there may be a problem in the fact that most ARIPO member countries, including Kenya, appear to routinely accept ARIPO patent applications without significant examination and, thereby, ARIPO standards may be gaining greater force

than intended. In addition, intellectual property rights authorities rarely consult with line ministries or lead agencies regarding the examination of patents and, therefore, have limited capacity to address some technical considerations and broader policy issues.

91 This is a treaty between Kenya, Uganda and Tanzania. The treaty was executed on 30th November 1999 and forms the basis for the Protocol on the Establishment of the East African Customs Union executed on 2nd March 2004.

92 This Common Market was created in 1995, succeeding the Preferential Trade Area (PTA) framework that had been established in 1991. The market consists of 20 countries: Angola, Burundi, Comoros, D.R. Congo, Djibouti, Egypt, Eritrea, Ethiopia, Kenya, Madagascar, Malawi, Mauritius, Namibia, Rwanda, Seychelles, Sudan, Swaziland, Uganda, Zambia and Zimbabwe.

93 Anyanzwa (2004).

94 See Lettington and Musungu (2000).

95 Even where these relate to pharmaceutical forms, rather than basic substances, they can still prove highly restrictive, partly depending on the policies adopted by KIPI.

96 Kenya has not undertaken a survey of what the patent, or mailbox, status is of these drugs in the countries where the country generally sources its imported generic drugs and active ingredients. Their status in China, India, South Africa and Pakistan is of particular importance.

97 This is of particular concern when one considers the increasing evidence that single dose nevirapine, which is itself under patent, and used in treatment to prevent mother to child transmission of HIV, creates resistance to nevirapine, and thus the standard first line triple therapy used in Kenya, in approximately 8% to 20% of the mothers treated. This means that the only sustainable option to prevent mother to child transmission may be triple therapy. Information provided by Dr. Chris Ouma of UNICEF in a presentation to the KCAEM in 2004.

98 Although this information is often difficult to access, with some information regarding mailbox applications having been regarded as confidential.

99 In the face of increased levels of resistance to existing malaria treatments, Kenya is planning to introduce a new combination product, Coartem. Coartem is under patent and, at its concessionary price, is expected to cost some 15 to 20 times the current costs of first line malaria treatments. In addition, the existence of the patent means that the long-term availability of the concessionary price and the consistency of the supply of the drug are subject to the goodwill of the patent holder and thus not guaranteed. Supplies of artemisinin have been raised as a possible influence on the cost and availability of Coartem but Kenya is already a producer of this raw material for use in other products and activities.

100 FDCs for the treatment of HIV/AIDS have primarily been pioneered by generic drug manufacturers. It is believed that brand name drug companies holding patents on the key drugs to be combined were not able to cooperate sufficiently to undertake the necessary research.

101 Confidential personal communications from two government officers, from separate institutions and on separate occasions in April 2004 expressed this general concept. The KCAEM is currently dormant and, therefore, not currently able to provide appropriate assistance.

102 Kaplan et al at 16 (2003).

103 Id at 17.

104 See Wanyanga (2004).