THE KENYAN ANTI-COUNTERFEIT REGULATIONS 2010

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The Anti Counterfeit Regulations 2010 (the "Regulations") were published subsequent to the Anti-Counterfeit Act of 2008 (the "Act") under legal notice no. 126/2010 on 27th August 2010 and come into force with immediate effect.

An intellectual property right is defined as any right protected under the Copyright Act, the Trade marks Act, the Seed and Plant Varieties Act and the Industrial Property Act hence extending protection to copyright, trademarks, designs, patents and plant breeders' rights. The Acts main positive advantage is that it establishes an Agency which will co-ordinate the fight against counterfeits across Kenya in an efficient and simple manner. However, it has been criticized for failing to provide for civil remedies, making it a requirement that an aggrieved person must establish that there has been infringement of an IP Act, failed to define "counterfeiting" adequately and provided that the Kenyan authorities have the option of returning the counterfeit goods to their country of origin rather than destroying them. The publication of the Regulations has now provided a mechanism for IP rights owners to use the Act to enforce their rights. Under the Regulations, Intellectual Property (IP) Right Owners can now submit particulars of their IP rights to the Anti-Counterfeit Agency (the "Agency") who will maintain a database of such particulars. This will enable the Agency to actively investigate and eliminate suspected counterfeit practices in Kenya. The Regulations also permit affected persons through their agents to report suspected counterfeit goods to the Agency, whose inspectors are empowered to search, seize and assess any breaches of the affected persons IP Rights.

The Pharmaceutical industry is among the key areas likely to be significantly affected by the Regulations. The raging debate about the implementation of the Regulations is that while on the one hand these Regulations will help protect Kenyan consumers against potentially harmful counterfeit medicines whilst affording protection to producers against unfair competition, on the other hand, the laws as drafted may be interpreted in a manner which may work as a barrier against the availability of more affordable and generic medicines that currently serve as a lifeline to a majority of the low income generating members of the country's population.

In determining the likely stance the Agency will take, it is vital to appreciate the definitions of what constitutes a counterfeit medicine under the Act and whether that definition could be reasonably interpreted to extend application to generic medicines.

In our analysis of the Act we note that it provides that the act of "Counterfeiting" means, in relation to medicine, taking the following actions without the authority of the owner of the intellectual property right subsisting in Kenya or elsewhere in respect of protected goods:

"The deliberate and fraudulent mislabelling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging."

The law goes further to define 'Counterfeit goods' under Section 2 of the Act to mean goods that are the result of counterfeiting and include any means used for purposes of counterfeiting.

The World Health Organisation (the "WHO") defines a 'generic medicine' as one 'which is a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights'. Having said that, the WHO defines a counterfeit medicine as a medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source. Generic medicines are made using similar or sufficient active and correct ingredients as those used by the innovator company's medicine and are sold under a brand which is different from the innovator company's brand for the particular medicine. They are equivalent versions of the originator medicine and provide the same quality safety and efficacy as the original brand name product having undergone strict scrutiny before they are licensed and given market approval by the relevant national medicines authority.

They are legally manufactured and sold with without descriptive representations regarding origin, authenticity or effectiveness. They are not counterfeit medicines.

That said, an analytical interpretation of the above provision of the Act would mean that it is possible that generic medicines may be labelled as counterfeit medicines. In addition, counterfeiting may apply to both branded and generic medicines. Counterfeit products may include products with the correct ingredients or the wrong ingredients, lacking active ingredients, with incorrect quantities of active ingredients, or with fake packaging. Therefore this provision does not give similar treatment to generic medicines as it does to the original innovator's medicines creating an unhealthy market in terms of competition. This provision is unconstitutional, contrary to fair trade practices and cannot qualify as consumer protection legislation.

The above scenario has been the subject of litigation in the Kenyan High Court in the case of Patricia Asero Ochieng', Maurine Atieno and Joseph Munyi versus The Republic (High Court Civil Suit No. 409 of 2009). In this case, the Petitioners filed a Petition seeking declarations that their fundamental rights under Sections 70 and 71 of the Kenyan Constitution were likely to be infringed with the implementation of the Act arguing that it limited access to affordable and essential drugs including HIV/AIDS generic drugs and that consequently the enforcement of the Act would infringe their constitutional rights.

They sought the staying of Sections 2, 32 and 34 of the ACA pending the hearing and determination of the Petition, and sought further orders that the Anti-Counterfeit Agency be restrained from enforcing Section 2, 32 and 34 of the Act as relates to generic drugs and medication as well as the importation of generic drugs and medicines. They argued that the sections deny persons infected with HIV/AIDS the right to access affordable and essential drugs and medication and this would jeopardize the availability of generic drugs and medication and hence infringe on their constitutional right to life.

They also argued that as Section 2 of the Act fails to provide a clear definition of what a "counterfeit" is, generic medicines may be misinterpreted to infer that they are counterfeits and further that Sections 2, 32 and 34 of the ACA had not taken into account Section 58(2) of the Industrial Property Act, which allows importation of generic drugs.

In making his decision, the learned judge noted that indeed Section 58(2) and 37 of the IPA and Section 2 of the Act were inconsistent in that the former sections allowed for parallel importation of generic medicines while at the same time the Act seemed to prohibit the importation of generic medicines into Kenya. He further noted that it is trite law that if an existing statutory provision is inconsistent with a latter statute, then the existing provision (Section 58 of IPA) takes precedence over the latter provisions (sections 2,32 and 34 of the Act).

He found that Section 2 of the ACA did not seem to distinguish medicines from other goods and that one needs to consider the right to life as enshrined in Section 71 of the Kenyan Constitution He stated that taking into account that women and children are most vulnerable to HIV/AIDS, the Act also had to be read in conjunction with the Children's Act (Act No. 8 of 2001) and other international instruments on the rights of the child and women. The learned judge further found that failure to get access to affordable generic ARV drugs and medicines will obviously adversely affect those infected with HIV and AIDS and many risk losing their lives.

After finding that the Petitioners had sufficiently demonstrated that the Petition is not frivolous and discloses an arguable case with chances of success, the learned judge granted an injunction staying the application and enforcement of Section 2, 32 and 34 of the Act as relates to the importation of generic drugs and medication and an injunction in the interim restraining the Anti-Counterfeit Agency from enforcing the same sections of the Act relating to the importation of generic drugs and medication pending the hearing and determination of the suit.

In conclusion, it is crucial to properly define the meaning of “counterfeits” in the Act and further draw the distinction between a ‘generic’ and a ‘counterfeit’ medicine as there is a tendency for the definitions to be used erroneously in an interchangeable and contradictory manner. In our view, there is no reason why a company manufacturing generic drugs may not continue to do so under the new Regulations provided they ensure that there is no deliberate and/or fraudulent mislabelling of the generic drug with regards to its identity or source.

The Kenya Bureau of Standards and not the Agency should look to assess, for example, where there are two similar drugs available on the market, both containing predominantly the same ingredients and manufactured for the same purpose such as HIV treatment, that they are distinguishable from the outset to a consumer thus enabling him/her to make an informative decision as to whether to purchase the ‘generic’ medicine which is normally available at a lower price or the more established brand. The only role the Agency should play is to prevent deliberate and/or fraudulent mislabelling of e generic medicines with regards to its identity or source. It is our view that, the Act needs to be amended to define counterfeiting of medicines as has been defined by the WHO; *“The deliberate and fraudulent mislabelling of medicine with respect to identity or source.”*

In light of the above, and as we await a final conclusion of the pending case in the High Court, it will be interesting to monitor the Agency’s stance towards producers and distributors of generic medicines as this will mark out the parameters that will be involved in the fight against counterfeit medicines.

JOHN SYEKEI
HAANEE KHAN