Patricia Asero Ochieng, Maurine Atieno and Joseph Munyi v The Republic

(High Court of Kenya, 20 April 2012）

Prepared by UNCTAD's Intellectual Property Unit

Case summary

The Kenyan High Court found that certain provisions of the Kenyan 2008 Anti-Counterfeit Act (hereinafter the Act) violate the right to life, human dignity and health as guaranteed under the Kenyan Constitution. The Court obliged the Kenyan Government to reconsider a provision of the Act to remedy the situation.

The facts: Section 2 of the 2008 Kenyan Anti-Counterfeit Act contains the following provision:

> "counterfeiting" means taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya or elsewhere in respect of protected goods—
>
> (a) the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;
>
> (b) the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his licence; […]
>
> (d) in relation to medicine, the deliberate and fraudulent mislabelling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging; Provided that nothing in this paragraph shall derogate from the existing provisions under the Industrial Property Act.

Section 32 of the Act makes it a criminal offense to possess, make, sell, etc. counterfeit goods. Section 35 *inter alia* provides imprisonment of a maximum of five years in the case of a first conviction, and a maximum of 15 years in the case of subsequent convictions. Section 34 of the Act provides intellectual property rights holders the right to request the seizure and detention of suspected counterfeit goods imported into Kenya. A number of HIV-positive Kenyan citizens seized the High Court for alleged incompatibility of Sections 2, 32 and 34 of the Act with the Kenyan Constitution, i.e. the right to life, human dignity and health, as these provisions are likely to affect their access to affordable and essential generic medicines. The main concern of the petitioners, who were supported by the United Nations Special Rapporteur on the right to health, related to a potential misunderstanding by Kenyan law enforcement authorities of the definition of "counterfeiting" under Section 2 of the Act, which could lead to the application of Section 2(a) to legitimate generic activities and would thus subject generic producers to sanctions like imprisonment and their products to seizures and detentions by customs authorities.

The legal issues:

In the Court's own words:

> "The crux of the dispute before this court is whether, by enacting section 2 in its present form, and by providing the enforcement provisions in sections 32 and 34 of the Anti-Counterfeit Act, the State is in violation of its duty to ensure conditions are in place under which its citizens can lead a healthy life; and whether these provisions will deny the petitioner access to essential medicines and thereby violate their rights under Articles 26(1), 28 and 43(1) [of the Kenyan Constitution], […]."[1]

The Court expressed the view that Section 2 of the Act is likely to be read as including generic products and would thus affect the availability of generic drugs in Kenya and threaten the petitioners' constitutional rights to life and health.[2] The Court acknowledged the specific proviso on medicines in Section 2, but considered it too vague to secure the above-mentioned constitutional rights

> "in a situation where those charged with the responsibility of enforcement of the law may not have a clear understanding of the difference between generic and counterfeit medicine."[3]

The Court thus implied that customs or police authorities may mistakenly apply Section 2(a) of the Act to legitimate generic activities. Such activities could relate to the generic manufacturing of originator products in the context of the regulatory review exception for early generic market entry and especially for the marketing of generic copies during the patent term in cases where the generic producer has reason to believe that the right holder's patent is weak and may be challenged in infringement litigation. Instead of applying Section 2(a), the correct interpretation of the Act would be to apply the special proviso on medicines, i.e. Section 2(d) of the Act. The latter provision in line with the TRIPS Agreement limits counterfeiting to acts of mislabeling. Due to unclear drafting of the provision, the relationship between paragraphs (a) and (d) may not seem entirely clear to juridical laypersons, e.g. customs officials or police authorities. This concerns in particular the question to what extent the unauthorized manufacture of copies of protected goods (i.e. para. (a)) may still apply to generic producers' activities, or whether paragraph (d) excludes paragraph (a) in the context of medicines.[4]

The Court in that context rejected the argument advanced by the Attorney General that the primary objective of the Act was to protect consumers from the use of counterfeit (i.e. mislabeled) medicines, so that correctly labeled generic drugs would not be seized and detained. According to the Court, the provisions of the Act on criminal sanctions (Section 32), on the IP holder's right to file a complaint against counterfeit products (Section 33) and on seizure and detention of suspected goods (Section 34) demonstrate that the true intention behind the Act is to protect IP rights, as opposed to patients' health.

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[1] Paragraph 67 of the judgment.
[2] Ibid, paragraph 78.
[3] Ibid, paragraph 84.
[4] See UNCTAD, *TRIPS Flexibilities and Anti-Counterfeit Legislation in Kenya and the East African Community: Implications for Generic Producers. An UNCTAD-UNIDO Discussion Paper*, New York and Geneva, 2016, pp. 13/14. Available at https://unctad.org/system/files/official-document/diaepcb2015d6_en.pdf

"Had the primary intention been to safeguard consumers from counterfeit medicine, then the Act should have laid greater emphasis on standards and quality."[5]

The Court obliged the government to redraft Section 2 of the Act to ensure its constitutional obligations.

Points of significance:

- The right to health may be invoked to oblige a government to ensure that IP enforcement provisions are not abused to limit access to legitimate generic medicines.
- The TRIPS Agreement limits the notion of counterfeiting to the intentional and unauthorized use of a trademark (Article 51, footnote 14). Expanding that scope to cover the unauthorized use of patents may affect generic activities, even when legitimate, but opposed by the patent holder (e.g. using the patented substance for marketing approval purposes).
- Criminal sanctions for patent infringement such as imprisonment may have chilling effects on generic activities. Civil remedies such as damages as provided under TRIPS (Article 45) are more appropriate.
- Customs authorities may not be in a position to determine patent infringement.

Key words: Counterfeiting; enforcement; customs; right to life; right to health.

Available at: http://kelinkenya.org/wp-content/uploads/2012/04/Judgment-Petition-No-409-of-20092.pdf

[5] Ibid, paragraph 82.