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Rethinking Patricia Asero Ochieng and Two Others v. The Attorney General and another

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ABSTRACT

In 2012, the High Court of Kenya at Nairobi declared Section 2 of the Anti-Counterfeit Act (ACA) unconstitutional because its enforcement would limit access to affordable and essential drugs and medicines and thereby undermine the right to life, human dignity and health as guaranteed under the Constitution of Kenya. This case review revisits this important judgement by Justice Mumbi Ngugi with the aim of analysing it for legal soundness. Further, this review discusses the likely impact of the judgement on the fight against counterfeit drugs and access to drugs in Kenya. On the other hand, there will be a comparison between Kenyan legal system and some foreign laws. The review argues that the judge applied the wrong legal principles in making her determination, arriving at a legally flawed conclusion, thereby nullifying the balance between the rights of intellectual property rights owners and users as established under the Industrial Property Act.

Keywords: Intellectual Property Rights, Generic Drugs, Parallel Imports, Proviso, Statutory Interpretation

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1. BACKGROUND

In 2012, the High Court of Kenya at Nairobi declared Section 2 of the *Anti-Counterfeit Act 2008* (ACA) unconstitutional on the basis that its enforcement would limit access to affordable and essential drugs and medicines and thereby undermine the right to life, human dignity and health as guaranteed under the Constitution of Kenya (P.AO. & 2 others v. Attorney General & another, 2012). As expected in a country with a high burden of HIV/AIDS infections,[1] the *Patricia Asero and 2 others v Attorney General and another* (2013) judgement by Justice Mumbi Ngugi was celebrated as very progressive (Njoki, 2017) because of the role that access to generic drugs and medicine plays in the fight against HIV/AIDS and other epidemics.[2] Reportedly, in Kenya, the cost of drugs accounts for more than half of the cost of healthcare due to overreliance on originator drugs, which account for 70% of all prescriptions (Njoki, 2017). Generic drugs are significantly cheaper

[1] As at 2018, Kenya had the third-largest HIV epidemic in the world with 1, 600, 000 people living with HIV. See Avert, 2019..

[2] According to UNAIDS (2019), "…[o]f all adults aged 15 years and over living with HIV, 69% were on treatment, while 61% of children aged 0–14 years living with HIV were on treatment." See *UNAIDS*, 2020. Increased access to Anti-Retroviral drugs in Sub-Saharan Africa has been attributed to the emergence of Indian pharmaceutical companies manufacturing generic drugs; Anita Hardon *et al.*, 2006 p. 25.

than their brand-name counterparts (sometimes 85% cheaper) because of reduced upfront research costs and the effect of the competition that they introduce in the market.[3]

In addition to persons living with HIV/AIDS, the judgement also carried a lot of significance for owners of intellectual property rights (IPRs) as it undermined their access to criminal law enforcement mechanisms for their rights. Further, the judgement had an impact on the local pharmaceutical sector, which though not fully developed, mainly produces generic drugs (UNIDO, 2010).

This case review revisits the judgement with the aim to analyse it so as to determine its legal soundness and the impact that it could have for IPRs-holders and users of rights. Despite its significance, no meaningful scholarship has been carried out in relation to the judgement. In fact, no legislative amendment has been introduced to bring Section 2 into conformity with the determination of the High Court. Thus, although this case review comes many years after the judgement was delivered, it hopes to reignite interest in the legal issues that were dealt with in the case. The relationship between IPRs and access to drugs remains an ever controversial issue in many developing countries including Kenya. This controversy is fuelled by a number of factors prevailing in developing countries: lack of meaningful manufacturing capabilities in the pharmaceuticals sector; most drugs sold in these territories are owned by companies from developed countries; and most of the countries are saddled with a heavy healthcare burden. This situation has been made worse by poverty and poor governance.

2. FACTS OF THE CASE

The case was initiated in 2009 by way of a Petition filed by three persons who claimed to be persons who had been living with HIV/AIDS for periods ranging from 8-19 years. The Petitioners stated that they received their medication free of charge from a Government-run programme. Being unemployed, they stated that they would not be in a position to afford the drugs by their own

[3] FDA, 2018.

means. They argued that sections 2, 32 and 34 of the ACA were likely to affect their access to affordable and essential drugs and medicines including generic versions and that this would amount to an infringement of their fundamental rights to life, human dignity and health as protected by articles 26(1), 28 and 43 of the Constitution. According to them, the impugned provisions of the ACA limited their access to generic drugs which had become easily available following the enactment of the Industrial Property Act (IPA) in 2001. Specifically, they asserted that the definition of "counterfeit goods" in the ACA was ambiguous and could be extended to include generic drugs. This would have prohibited importation and manufacture of generic drugs and medicines in Kenya by making them liable to seizure, and thus, limiting access to essential drugs in Kenya for people who relied on generic drugs.

The Petitioners sought the following prayers from the court:

(a) A declaration that the fundamental right to life, human dignity and health as protected and envisaged by Articles 26(1), 28 and 43 of the Constitution encompasses access to affordable and essential drugs and medicines including generic drugs and medicines.

(b) A declaration that in so far as the Anti Counterfeit Act, 2008 severely limits access to affordable and essential drugs and medicines including generic medicines for HIV and AIDS, it infringes on petitioners right to life, human dignity and health guaranteed under Articles 26(1), 28 and 43 of the Constitution.

(c) A declaration that enforcement of the Anti-Counterfeit Act, 2008 in so far as it affects access to affordable and essential drugs and medication particularly generic drugs is a breach of the petitioner's right to life, human dignity and health guaranteed under the Constitution.

(d) Any further orders, directions, declarations and remedies as this honourable court may deem fit and just in the circumstances.

Aids Law Project (a Non-Governmental Organisation registered in Kenya) joined the suit as an Interested Party while Mr Anand Grover, the United Nations Special Rapporteur for

Health participated in the Petition as *Amicus Curiae*. They both supported the Petitioners' case.

The Respondents, who were the Attorney General, sued as the principal legal advisor of the Government, and the Anti-Counterfeit Agency,[4] sued as the entity charged with the responsibility to enforce the provisions of the ACA, opposed the Petition. The central plank of the Respondents' case was that the purpose of the ACA was to prohibit trade in counterfeits in Kenya and did not in any way target generic drugs. Further, the Respondents argued that the definitions of "counterfeit medicines" and "generic drugs" as contained in the ACA were in line with those of the World Health Organisation (WHO) (Velasquez *et al.*, 1999) and did not exhibit any ambiguity as the Petitioners alleged.

3. ISSUES IN DISPUTE AND COURT'S DETERMINATION

Based on the parties' pleadings, the court characterised the issues in dispute as follows:

> The crux of the dispute before this court is whether, by enacting sections 2 (sic) in its present form, and by providing the enforcement provisions in section 32 and 34 (sic) 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 petitioners access to essential medicines and thereby violate their rights under articles 26(1), 28 and 43(1), as well as sections 53 with regard to the rights of children.

The provisions to which this dispute related are set out below. First, the Anti-Counterfeit Act, Section 2, read as follows:

> 'counterfeiting' means taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya or elsewhere[5] in respect of protected goods–

[4] This entity was later renamed the Anti-Counterfeit Authority through the Statute Law (Miscellaneous Amendments) Act, 2018.

[5] The words 'or elsewhere' were deleted from the definition of 'counterfeiting' through an amendment introduced by Statute Law (Miscellaneous Amendments) Act, 20I4; subsequent amendments through Statute Law (Miscellaneous Amendments) Act, 2018, inserted the words 'or, outside Kenya' in their place'.

(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;

(c) the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author's rights or related rights;

(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, 2001 (No 3 of 2001).

The Anti-Counterfeit Act, Section 32, at the time read as follows:[6]

It shall be an offence for any person to–

(a) have in his possession or control in the course of trade, any counterfeit goods;

(b) manufacture, produce or make in the course of trade, any counterfeit goods;

(c) sell, hire out, barter or exchange, or offer or expose for sale, hiring out, barter or exchange any counterfeit goods;

(d) expose or exhibit for the purposes of trade any counterfeit goods;

(e) distribute counterfeit goods for purposes of trade or any other purpose;

(f) import into, transit through, transship within or export from Kenya, except for private and domestic use of the importer or exporter as the case may be, any counterfeit goods;

(g) in any other manner, dispose of any counterfeit goods in the course of trade;

[6] This section was amended by Statute Law (Miscellaneous Amendments) Act, 2018, which introduced additional offences as paragraphs (h)-(n).

The Anti-Counterfeit Act, Section 34, read as follows:[7]

> (1) The owner of an intellectual property right, who has valid grounds for suspecting that the importation of counterfeit goods may take place, may apply to the Commissioner in the prescribed manner to seize and detain all suspected counterfeit goods which are–
>
> (a) goods featuring, bearing, embodying or incorporating the subject matter of that intellectual property right or to which the subject matter of that right has been applied; and
>
> (b) imported into or enter Kenya during the period specified in the application:
>
> Provided that the period may not extend beyond the last day of the period for which that intellectual property right subsists.

On the other hand, the relevant articles of the Constitution were as follows: Article 26 which guarantees every person the right to life; Article 28 which guarantees inherent dignity and the right to have that dignity respected and protected; Article 43 which guarantees the right to the highest attainable standard of health, and Article 53 which guarantees every child the right to basic nutrition, shelter and health care as well as provides for a child's best interests.

4. DETERMINATION

After analysing the evidence presented and the submissions made by the parties, the judge made findings in favour of the Petitioners in the following terms:

> In view of the matters set out above, I find that sections 2, 32 and 34 of the Anti- Counterfeit Act threaten to violate the right to life of the petitioners as protected by Article 26 (1), the right to human dignity guaranteed under Article 28 and the right to the highest attainable standard of health guaranteed under Article 43 (1) and grant the declarations sought…

On the first issue on whether Section 2 of the ACA was ambiguous, the judge agreed with the Petitioners' submissions, the

[7] This Section was amended by Statute Law (Miscellaneous Amendments) Act, 2018.

Interested Party and the *Amicus Curiae* that the section conflated "generic drugs" with "counterfeit drugs". In justifying this finding, the judge observed that there had, indeed, been cases of generic drugs being seized in other jurisdictions on allegations that they were counterfeit. To further explain its finding in this regard, the judge observed that so far as Section 2 of the ACA uses the words "whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging," then the definition of "counterfeiting" necessarily covered "generic drugs" because generic drugs "have correct ingredients …" and "sufficient active ingredients" as defined, in the opinion of the judge, by the WHO.

On the second issue whether the enforcement of Section 2 of the ACA through sections 32 and 34 would deny the Petitioners access to essential medicines and thereby violate their rights under articles 26(1), 28, 43(1) and 53, the High Court observed as follows:

> I would therefore agree with the Amicus that the definition "would encompass generic medicines produced in Kenya and elsewhere and thus is likely to adversely affect the manufacture, sale, and distribution of generic equivalents of patented drugs. This would affect the availability of the generic drugs and thus pose a real threat to the petitioners' right to life, dignity and health under the Constitution".

5. Key Obiter Dicta Statements

In delivering her judgement in this case, Justice Ngugi made some statements which though not forming the *ratio decidendi* of the judgement, are, nevertheless, worth highlighting. These statements constituted *obiter dicta.*

Firstly, in paragraph 83 of the judgement, the judge took issue with the fact that the ACA had prioritised the enforcement of IPRs in dealing with the problem of counterfeit medicine. In the judge's view, the ACA should "…have taken an approach focused on quality and standards" so as to safeguard the interests of consumers instead of making this a collateral goal. Secondly, in paragraph 85 of the judgement, the judge dismissed an argument by the Respondents that the ACA preserved rights granted under

the IPA through a *proviso* appearing at the end of the definition of the word "counterfeiting". According to her, the ACA being later in time would have prevailed over the IPA despite a proviso specifically preserving rights under the Act. Thirdly, in paragraphs 85 and 86, the judge expressed her opinion on how to resolve a conflict between the protection of the rights to life, dignity and health, on one hand, and the right to property in the form of IPRs, on the hand. In an off-hand manner, the judge declared that in such a case, the first group of rights would take precedence because they are "…far greater and more critical than the protection of the intellectual property rights."

6. COMMENTARY

Justice Ngugi based her judgement on the wrong legal principles, and as such, her judgement in this case must be treated as bad law. This review attacks the judgement from three angles: the judge's apparent misapprehension of some IPRs concepts; the judge's misapplication of the rules of statutory interpretation; and judge's proposal for wrongful abrogation of the right to property.

6.1. Misapprehension of Concepts

Firstly, Justice Ngugi appears not to have mastered the difference between generic drugs and parallel import drugs.[8] Generic drugs and parallel import drugs, though related and sometimes overlaps exist, arise from dissimilar set of facts.

The World Trade Organisation (WTO) (2006) defines the term "generic" in relation to IPRs from two points of view: trade mark protection and patent protection. From a trademark protection point of view, a generic product would be one without a trademark. From a patent protection point of view, a generic product is defined as a copy of patented products whose patent has expired. On its part, the WHO defines generic medicines as "those produced without a licence from the innovator company when the patent or

[8] See paragraph 50 and 51 of the judgement.

other market exclusivity rights on the innovator product has expired" (World Health Organisation, 2016). Evidently, generic drugs would fall outside the scope of Section 2 of the ACA because they would not meet the requirement of having been manufactured, produced, made or deliberately and fraudulently mislabelled without the authority of the owner of the IPR subsisting in Kenya or elsewhere. The patent or other form of market exclusivity would have ceased to exist.

Parallel imports refer to goods produced and sold legally by the IPRs-holder or under their licence in one territory which are then exported to another territory by third parties or outside the distribution channels provided by the rights holder (Heath, 1997). Parallel importers seek to take advantage of price difference of products in various countries. In the context of drugs, a parallel importer could import protected drugs from a low-price country into a high-price country and then offer them at lower prices than the local price set by the patentee or trademark owner. Naturally, having been produced and sold legally in one territory, parallel imports would not qualify as having been manufactured, produced, made or deliberately and fraudulently mislabelled without the authority of the owner of the IPR subsisting in Kenya or elsewhere. Additionally, parallel imports are provided for under the IPA (s. 58(2)).

Secondly, the judge appeared not to have understood the purpose of the ACA fully and the way in which it could protect the public from substandard and harmful products. According to the judge, the ACA had prioritised the enforcement of IPRs in dealing with the problem of counterfeit medicine wrongly instead of taking an approach focused on quality and standards.

In its long title, the ACA explicitly set out its objective as being "[a]n Act of Parliament to prohibit trade in counterfeit goods, to establish the Anti-Counterfeit Agency and for connected purposes". In essence, the ACA was enacted to introduce an additional (penal) enforcement mechanism for IPRs-holders without creating any new substantive rights. Substantive IPRs are created through legislations like the IPA, the Trade Marks Act and the Copyright Act. The question of quality and standards for medicine is dealt

with by other legislations like the Food, Drugs and Chemical Substances Act, the Competition Act, the Consumer Protection Act and the Standards Act. Thus, in making this comment, the judge not only misapprehended the objective of the ACA, she also strayed into the arena of legislation and policy-making.

Establishment of criminal or penal enforcement mechanisms for IPRs, although not strictly required by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) for all rights other than for wilful trade mark counterfeiting and copyright piracy on a commercial scale (Omolo, 2018), provides an additional arsenal for rights holders to enforce their rights. A stronger legal regime for the enforcement of IPRs necessarily bolsters the war against counterfeiting. Suppression of counterfeiting serves public interest by ensuring that there are no fraudulent free riders and that the genuine originators and owners of products are credibly identified. Identification of the genuine originators and owners of products assures consumers about their legitimacy and ensures that in cases of injury or loss, after-sales services and opportunity for effective recourse remain available (Blakeney, 2004, p. 8).

6.3. Wrongful Abrogation of the Right to Property

In paragraphs 85 and 86, the judge expressed her opinion on how to resolve a conflict between the protection of the rights to life, dignity and health and the right to property in the form of IPRs. In an off-hand manner, the judge declared that in such a case, the first group of rights would take precedence because they are "…far greater and more critical than the protection of the intellectual property rights". In making this conclusion, the judge (without providing more details) appears to have suggested that IPRs can be abrogated unconditionally when they hinder the protection of the rights to life, dignity and health.

The Constitution defines "property" to include any vested or contingent right to, or interest in or arising from— (c) intellectual property (a. 260). In Article 40, the Constitution provides for the right to property as one of its rights and fundamental freedoms. Under Article 24, the right to property, just like the rights to life,

dignity and health, fall within a group of rights that may be limited. However, the Article stipulates a number of conditions that must be met before a right may be limited: limitation must be by law; and limitation must be reasonable and justifiable in an open and democratic society. Further, the Constitution (under Article 40) provides clarity on the limitation of the right to property. It prohibits any law that is discriminatory or that arbitrarily deprives a person of his property. Where deprivation is by the State, the Constitution only anticipates: instances where acquisition is done according to its provisions; is done for public purpose or in the public interest; and is done under the Constitution or an Act of Parliament providing for prompt payment of just compensation and grants right of access to a court of law.[9]

Thus, to resolve a conflict between the protection of the rights to life, dignity and health and the right to property in the form of IPRs, one must carry out a proper analysis using the relevant laws. It cannot be taken for granted that the right to property would invariably and unconditionally give way.

6.2. Misapplication of the Rules of Statutory Interpretation

In the course of making her determination, Justice Ngugi misapplied the rules of statutory interpretation in two instances thereby leading to wrong conclusions.

Firstly, one of the issues that the court was called upon to make a determination on was whether Section 2 of the ACA made an ambiguous provision for the definition of "counterfeiting". Indeed, the High Court found that the section was ambiguous as it conflated 'generic drugs' with "counterfeit drugs". To justify its finding, the High Court noted that because Section 2 of the ACA uses the words "whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging", then the definition of "counterfeiting" necessarily covered "generic drugs" because "generic drugs" "have correct ingredients…" and "sufficient active ingredients" as defined

[9] The Industrial Property Act provide additional safeguard by way of provisions on compulsory licensing which can also be used to balance public interest and private property rights.

by WHO. This interpretation of paragraph 2(e) of the ACA is erroneous.

The definition of counterfeiting in relation to medicine under Section 2 of the ACA had three key elements: taking certain actions, being the deliberate and fraudulent mislabelling with respect to identity or source; lack of authority of the owner of IPRs; and the existence of protected goods. By way of clarification, paragraph 2(d) of the ACA indicated that once the three elements identified above have been satisfied then the definition of counterfeiting would have been met "...whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging..." From a literal interpretation approach, even without this additional information, paragraph 2(d) of the ACA was clear in its meaning. However, the judge ignored all the key elements of the definition and instead only concentrated on the illustrative part of the paragraph, which she said would cover generic drugs as defined by the WHO. The judge outlined this definition in paragraph 77 of the judgement, thus:

> "...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*" (Emphasis added).

In other words, in the opinion of the judge, drugs with correct ingredients or sufficient active ingredients cannot be condemned as counterfeit even where their source and identity have been deliberately and fraudulently mislabelled and where they have been made or distributed without the authority of the proprietor of the IPR(s) embedded in them! A drug would have been deliberately and fraudulently mislabelled as to identity or source where one, intentionally and with the aim to deceive, misascribes its manufacturer or distributor or profile. Where a drug has been deliberately and fraudulently mislabelled as to identity or source, it becomes counterfeit irrespective of its quality.

Secondly, the High Court made a wrong determination on the effect of the proviso appearing in Section 2 of the ACA. In their defence, the Respondents argued that the definition of counterfeiting in the ACA was subservient to the provisions of the IPA. In the context of the present case, the Respondents' argument was that the IPA already provided for parallel imports and term limits for IPRs and that such provisions remained valid despite the enactment of the ACA on account of the proviso to Section 2.

The judge rejected this argument on two grounds: the *proviso* was vague; and the ACA, being later in time, would prevail over the IPA.

On vagueness, the judge provided no explanation on what aspect of the proviso was vague. However, more fundamentally, the judge improperly discounted the effect of the proviso on the interpretation of Section 2. A proviso is one of the intrinsic interpretation aids incorporated into a statute. The main function of a proviso is to limit or clarify the scope of a provision. It limits the unintended application of the provisions of a statute to certain circumstances. In *Commissioner of Income-Tax, Mysore, Travancore-Cochin and Coorg v Indo-Mercantile Bank Ltd* (1959), the Supreme Court of India summarised the function of a proviso, thus:

> "The proper function of a proviso is that it qualifies the generality of the main enactment by providing an exception and taking out as it were, from the main enactment a portion which, but for the proviso, would fall within the main enactment. Ordinarily, it is foreign to the proper function of a proviso to read it as providing something by way of an addendum or dealing with a subject which is foreign to the main enactment. It is a fundamental rule of construction that a proviso must be considered with relation to the principal matter to which it stands as a proviso. Therefore, it is to be construed harmoniously with the main enactment".

A reading of Section 2 of the ACA does not reveal any conflict with the provisions of the IPA. As such, the proviso was, in reality, superfluous. However, in her judgement, the judge not only ignored the natural meaning derived from the section, she omitted to give meaning to the proviso so as to dispel any doubts that she may have entertained on the relationship between the ACA and the

IPA.[10]Although it is true that the ACA was enacted later than the IPA, the proviso, effectively, saved the provisions of the earlier legislation on the nature and extent of IPRs. It sought to signal that the definition of counterfeiting had to be understood in the broader framework as established under the IPA.

7. CONCLUSION

This case review set out to discuss an old but important decision by the High Court of Kenya. While the author salutes the noble aspiration of the High Court to ensure enhanced access to healthcare by allowing unrestricted supply of generic drugs, the decision lacks legal backing. In the long run, this decision could be inimical to the interests of both users and local manufacturers of generic drugs as counterfeiting targets both generic and innovator drugs.

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[10] See *Abdi Karim Mohamed and Another v Republic* (2006) eKLR for a discussion on the failure of a trial court to fully apply the *provisos* to section 214(1) of the Criminal Procedure Code; and *East African Centre for Trade Policy and Law v Secretary General of the East African Community* (2013) eKLR for a discussion on how introduction of provisos to articles 27(1) and 30(3) of the Treaty for the Establishment of the East African Community affected the jurisdiction of the East African Court of Justice.

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