

**REPUBLIC OF KENYA**

**IN THE HIGH COURT OF KENYA AT NAIROBI**

**PETITION NUMBER 97 OF 2010**

**IN THE MATTER OF CONTRAVENTION OF ARTICLES 26(1), 28 and  
43 OF THE CONSTITUTION OF KENYA**

**AND**

**ANTI-COUNTERFEIT ACT, 2008 (ACT NO. 13 OF 2008)**

**AND**

**IN THE MATTER OF CONTRAVENTION OF FUNDAMENTAL RIGHTS  
AND FREEDOMS UNDER ARTICLE 21 OF THE CONSTITUTION OF  
KENYA**

**BETWEEN**

**AIDS LAW PROJECT =====PETITIONER/APPLICANT**

**AND**

**THE ATTORNEY GENERAL=====1<sup>st</sup> RESPONDENT  
THE DIRECTOR OF PUBLIC PROSECTIONS =====2<sup>nd</sup> RESPONDENT**

**AND**

**MR ANAND GROVER, UN SPECIAL RAPPORTEUR FOR  
HEALTH=====AMICUS CURIAE**

---

**WRITTEN SUBMISSIONS**

1. Prior to the enactment of the *Industrial Property Act* (No. 3 of 2001), generic drugs for the treatment of HIV and AIDS were not available in the country because the previous existing legislation did not allow for parallel importation of generic drugs and medicines (that is, section 36 of the *Industrial Property Act* (Cap 509)). This situation changed after the enactment of section 58 (2) of the *Industrial Property Act 2001*, read with Rule 37 of the *Industrial Property Regulations 2002*, which currently allows for parallel importation of generic drugs.
2. In 2008, the Kenyan Parliament enacted the *Anti-Counterfeit Act* (No. 13 of 2008) whose objective is to prohibit trade in “counterfeit goods”. The Act was

assented to by the President on 24th of December 2008. Legal Notice No. 115 gives notice of commencement of the Act as 7th July 2009. Sections 2, 32 and 34 of the Act, read together, render the antiretroviral medication used by patients being treated for HIV/AIDS counterfeit. As such, their continued usage is illegal and became criminal activity when the Act was commenced.

3. As such, the enforcement and application of the *Anti-Counterfeit Act* (No. 13 of 2008), particularly sections 2, 32 and 34, will endanger the lives of Kenyan citizens afflicted with HIV and AIDS, as they will be arbitrarily denied access to affordable and essential drugs and medication necessary for the fulfillment of the rights to life and human dignity that are enshrined in Articles 26, 28 and 43 of the Constitution of the Republic of Kenya.
4. The Special Rapporteur make submission in this matter to support the constitutional principles of access to essential medicines as they are contained in the following provisions of the *Industrial Property Act* (No. 3 of 2001), inter alia:
  - a. Section 80(1)(a) on exploitation of the patented inventions by the Government, or by third parties authorized by the Government, ;
  - b. Section 80(1A) and (1B), which deal with generic substitution and compulsory licences issued to third parties;
5. The subject matter of this petition clearly falls within the mandate of the Special Rapporteur, and the scale of HIV/AIDS epidemic and its impact on society, together with the constitutional issues pertaining to access to life-saving essential medicines for people living with HIV and AIDS, form the basis of the Special Rapporteur's interest in the these proceedings.

#### **THE MANDATE OF THE SPECIAL RAPPORTEUR**

6. As the United Nations Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Mr Grover is obliged to fulfil certain tasks in accordance with his mandate including, inter alia:-
  - a. To gather, request, receive and exchange information from all relevant sources, including Governments, intergovernmental and non-governmental organizations, on the realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, as well as policies designed to achieve the health-related Millennium Development Goals;
  - b. To develop a regular dialogue and discuss possible areas of cooperation with all relevant actors, including Governments, relevant United Nations bodies, specialized agencies and programmes, in

particular the World Health Organization and the Joint United Nations Programme on HIV/AIDS, as well as non-governmental organizations and international financial institutions;

- c. To report on the status, throughout the world, of the realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and on developments relating to this right, including on laws, policies and good practices most beneficial to its enjoyment and obstacles encountered domestically and internationally to its implementation;
- d. To make recommendations on appropriate measures to promote and protect the realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, with a view to supporting States' efforts to enhance public health.

7. In turn, all States are called upon to, inter alia: -

- a. Give due consideration to the recommendations of the Special Rapporteur;
- b. Guarantee that the right of everyone to the enjoyment of the highest attainable standard of physical and mental health will be exercised without discrimination of any kind;
- c. Ensure that relevant legislation, regulations and national and international policies take due account of the realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health;
- d. Take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of their available resources, with a view to achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health;
- e. To take into account the fact that access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria is a fundamental element for achieving progressively the full realization of the right to health.

8. In appearing in this matter, the Special Rapporteur is acting in fulfilment of the mandate issued by the United Nations Human Rights Council. The mandate, as outlined in Human Rights Council Resolution 6/29 (**annexure 1**), obliges the Rapporteur to make recommendations on issues surrounding the Right to Health, particularly in relation to laws, policies and practices that may represent obstacles to the Right being realised.

## **APPLICABLE LAW**

### **APPLICATION OF CONSTITUTIONAL AND INTERNATIONAL LAW IN PROTECTION OF THE RIGHT TO HEALTH**

#### *International law*

9. The right to the highest attainable standard of mental and physical health includes the right to access medicines, as provided by international covenants to which the Government of the Republic of Kenya has acceded. Under the International Covenant on Economic, Social and Cultural Rights (“ICESCR”), which Kenya acceded to on 1 May 1972, States have core obligations to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant. This includes the right to the highest attainable standard of physical and mental health under Article 12, to which the Republic of Kenya expressed no reservations. Additionally, Article 24 of the Convention on the Rights of the Child (“CRC”), ratified by the Kenyan Government on 30 July 1990 provides for the right of the child to the highest attainable standard of health.
10. It is clear that, under Kenyan law, “treaty law can be applied by State Courts where there is no conflict with existing state law, even in the absence of implementing legislation”.<sup>1</sup> The High Court has also recognized the obligation of domestic courts to directly fulfil the obligations accrued under international conventions, irrespective of incorporation. In *Republic v. Minister for Home Affairs Ex-parte Sitamze*, it was noted that: “[t]o give effect to the human rights provided for under the International Covenant on Economic, Social and Cultural Rights, 1966, the Court should interpret the Constitution generously...[and] bear in mind that the rights under the Covenant are intended to be guaranteed by each party state and effectively redressed whenever infringed.”<sup>2</sup>

#### *Constitutional law*

11. Section 43(1) of the newly-enacted Constitution of Kenya states that “Every person has the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care.” Article 53 of the Constitution of Kenya further guarantees the right of every child to “basic nutrition, shelter and healthcare”.

---

<sup>1</sup> *Rono v Rono and Another*, Civil Appeal No. 66 of 2002, Court of Appeal of Kenya at Eldorat, (2008) 1 K.L.R. (G & F) 803, 813.

<sup>2</sup> *Republic v. Minister for Home Affairs & Others, Ex Parte Sitamze*, Misc. Civil Case No. 1652 of 2004, High Court of Kenya at Nairobi, [2008] e K.L.R.,

- 12.** As Kenya is a dualist nation, and the language of these constitutional guarantees largely echo that of the ICESCR and CRC respectively, interpretation of these constitutional provisions should be informed and guided by international law, even if no express intention to incorporate the terms of the treaties is evinced within the Constitution itself.
- 13.** In any event, if the rights accrued by citizens under Sections 43 and 53 of the Kenyan Constitution are not held to be coextensive with the rights accrued under the ICESCR and the CRC, any violations of those international conventions will nonetheless stand. A state party may not invoke the provisions of its internal law as justification for its failure to perform a treaty,<sup>3</sup> so any failure to fully incorporate the provisions of either international convention will be no excuse for a violation at international law.
- 14.** Moreover, the High Court of Kenya has held that “constitutional rights and especially human rights and freedom are interdependent and indivisible” – in accordance with international human rights law<sup>4</sup> – and that “their interplay has to be fully reflected...in every field allocated power by the Constitution.”<sup>5</sup> The specific link between the constitutional right to life, and social, economic and cultural rights was also recognized by the High Court prior to the introduction of the new Constitution.<sup>6</sup> As such, existing domestic jurisprudence concerning the right to life, espoused in the previous constitution, can guide interpretation of Sections 26, 28 and 43, all of which are interdependent.

## **THE RIGHT TO HEALTH AND ACCESS TO MEDICINES**

- 15.** The right to the highest attainable standard of health, as outlined in Article 12 of the ICESCR, imposes core obligations on States to respect, protect and fulfill the right to health and to ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups. Medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central features of the right to health, the realization of which depends upon access to medicines.
- 16.** Article 12(2) outlines specific steps that State Parties to the ICESCR are obliged to take to achieve the full realization of the right. Article 12(2)(c) provides that States must take steps to ensure “[t]he prevention, treatment

---

<sup>3</sup> Article 27, Vienna Convention on the Law of Treaties (1969).

<sup>4</sup> Vienna Declaration and Program of Action (1993), A/CONF.157/23.

<sup>5</sup> *Lemeiguran v. Attorney General*, Misc. Civil Application No. 305 of 2004, High Court of Kenya at Nairobi, (2008) 3 K.L.R. (EP) 325, 364.

<sup>6</sup> *Republic v. Minister for Home Affairs & Others, Ex Parte Sitamze*, Misc. Civil Case No. 1652 of 2004, High Court of Kenya at Nairobi, [2008] e K.L.R.,

and control of epidemic, endemic, occupational and other diseases”. As HIV/AIDS has reached epidemic proportions within Kenya, this article is certainly applicable to the State. The prevalence of HIV in adults aged 15-49 years was estimated to be 7.4 percent in 2007, and around 1.4 million adults aged 15-64 are estimated to be infected.<sup>7</sup>

**17.** Additionally, 12(2)(d) requires “[t]he creation of conditions which would assure to all medical service and medical attention in the event of sickness”.<sup>8</sup> This latter clause has been interpreted by the Committee on Economic, Social and Cultural Rights (“CESCR”), in their General Comment No 14, to include provision of essential drugs.<sup>9</sup> The General Comment directly elaborates upon, and gives further content to, Article 12 of the ICESCR. As such, it should also be utilized to interpret the constitutional right to health in Kenya, as contained in Section 43(1) of the Constitution.

**18.** The General Comment states that the right to health at all levels contains the essential elements of accessibility to health facilities, goods and services. Accessibility has four dimensions: non-discrimination, physical accessibility, affordability and information accessibility. In the context of access to medicines, this requires States to ensure that at least essential drugs, as defined by the WHO Action Programme on Essential Drugs, are available, financially affordable, physically accessible, culturally acceptable, and of good quality.<sup>10</sup> Each of the drugs required for first-line treatment for HIV are included in the list of Essential Drugs. Therefore, access to medicines, including combination therapy for HIV/AIDS, forms an indispensable part of the right to health which the Republic of Kenya has agreed to fulfill – and, indeed, is obligated to fulfill under its Constitution, as informed and supplemented by binding international law.

**19.** Although the ICESCR recognizes the right of every “to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author”,<sup>11</sup> General Comment No 17 of the CESCR emphasizes that this cannot be isolated from other rights contained in the Covenant, and in order to promote and protect the full range of rights, a balance must be found. A state’s protection of

---

<sup>7</sup> Kenya National Bureau of Statistics, “Kenya Demographic and Health Survey 2008-2009” (Nairobi, 2010), p 210.

<sup>8</sup> International Covenant on Economic, Social and Cultural Rights, art. 12(2), adopted Dec. 16, 1966, 993 U.N.T.S. 3, entered into force Jan. 3, 1976, available at <http://www2.ohchr.org/english/law/cescr.htm>

<sup>9</sup> Committee on Economic, Social and Cultural Rights (“CESCR”), General Comment 14, para 17. E/C.12/2000/4.

<sup>10</sup> *Ibid.*, para 12(a).

<sup>11</sup> ICESCR, Article 15(1)(c).

material interests resulting from scientific production should not impede their “ability to comply with their core obligations in relation to the rights to food, health and education”. As such, the CESCR has indicated that an author’s right to benefit from their innovation does not prevail over the State’s obligation to ensure access to essential medicines. Indeed the CESCR noted that intellectual property is ultimately a social product, and that “State parties thus have a duty to prevent unreasonably high costs for access to essential medicines.”<sup>12</sup>

- 20.** General Comment No. 3 of the Committee on the Rights of the Child expands upon Article 24 of the CRC. It specifically states that States have an obligation to ensure children have equal access to treatment and care including “necessary HIV-related drugs and goods and services”, and that parties to the convention should “negotiate with the pharmaceutical industry in order to make the necessary medicines locally available at the lowest costs possible”.<sup>13</sup>

### **THE ANTI-COUNTERFEITING LAW AND ACCESS TO MEDICINES**

- 21.** The objective of the *Anti-Counterfeit Act* (No. 13 of 2008) is to prohibit trade in counterfeit goods. This act endangers the constitutional right to health afforded to the citizens of the Republic of Kenya, and in turn, the right to life, as guaranteed under sections 26 and 43 of the Constitution respectively. The *Anti-Counterfeit Act* is likely to affect patients’ access to generic, therapeutic equivalents of drugs that are patented in the Republic of Kenya, or elsewhere.

- 22.** Section 2 of the *Anti-Counterfeit Act* defines “counterfeiting” as taking of the following actions without authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods-
- a.** the manufacture, production, packaging, repackaging, labeling, or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such 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 IP, or a colourable imitation thereof so that the other goods are calculated to be confused with or taken as being the protected goods of the said owner of any good manufactured, produced or made under his licence;

---

<sup>12</sup> CESCR, General Comment No. 17, para 35. E/C.12/GC/17

<sup>13</sup> Committee on the Rights of the Child, General Comment No. 3, para 28. CRC/GC/2003/3.

- 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 mislabeling 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 IP Act.

- 23.** A generic medication is defined by the World Health Organisation as “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”.<sup>14</sup> They have the same composition and contain the same substances as patented formulations of the same drug, and are essentially identical copies.
- 24.** It is precisely this fact that affords more people access to quality medicines, as generic medicines are identical yet substantially cheaper, and therefore significantly more affordable than their patented counterparts. Generic medicines are up to 90% cheaper than branded medicines, and therefore enable equitable access to medicines without discrimination on the basis of income. To ensure that the principle of non-discrimination outlined in Section 27 of the Constitution, and Article 2 of the ICESCR, is adhered to, it cannot be permissible that poorer households are disproportionately burdened with health expenses as compared to richer households.
- 25.** Generic medicines are necessary in Kenya for purposes of the realization of the right to health, even if the product in question is patented. This is to ensure that patients can access required medications even in the event that the patented product is not available in sufficient quantities or at affordable prices, or in case a compulsory license has been issued.
- 26.** On the other hand, the World Health Organisation defines counterfeit drugs as “medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source”, and may be compounded using the wrong ingredients, insufficient active ingredients, without active ingredients altogether, or with fake packaging.<sup>15</sup> These counterfeit drugs represent a threat to health, in that

---

<sup>14</sup> WHO, “Trade, foreign policy, diplomacy and health: Generic Drugs”. Accessed at: <http://www.who.int/trade/glossary/story034/en/index.html>

<sup>15</sup> WHO, “Medicines: Counterfeit Medicines”. Fact Sheet No. 275, January 2010, Geneva. Accessed at: <http://www.who.int/mediacentre/factsheets/fs275/en/>



they can have adverse consequences if the wrong ingredient is included, or can fail to produce the required physiological effect if compounded incorrectly.

- 27.** The definition of “counterfeiting” in the *Anti-Counterfeit Act* (No. 13 of 2008), includes this information in subsection (d). However, it also goes further, to include “manufacture, production...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” in subsection (a). A definition of this breadth would certainly 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. The definition provided in the *Anti-Counterfeiting Act* does not include an exception for medications, and does not avert to the existence of generic drugs.
- 28.** This definition of ‘counterfeiting’ within the *Act* effectively conflates public health concerns vis-a-vis medicines with possible violations of private intellectual property rights. This conflation of intellectual property rights issues with public health issues will have a serious adverse impact on the availability, affordability and accessibility of medicines, especially generic medicines
- 29.** The implications of the inclusion of generic medicines in the definition of ‘counterfeiting’ are potentially as follows:
- a. Seizure of medicines within Kenya that are approved by regulatory authorities as being safe and effective, on the grounds of allegedly being “counterfeit”, and their removal from the market;
  - b. Seizure of generic medications at foreign ports that are due to be imported to Kenya, due to uncertainty surrounding possible infringement of the *Act* upon delivery;
  - c. Significant delays of shipments of imported generic drugs at ports of entry to Kenya, for inspection/legal clarification purposes;
  - d. Seizure of medicines at Kenyan ports of entry by customs officials and police officers, who are not specially trained to recognise the difference between counterfeit and generic products;
  - e. Increases in the price of ARVs within Kenya due to the aforementioned seizures and delays reducing market competition, substantially reducing the financial accessibility of these medications.

## **KENYAN INTELLECTUAL PROPERTY LAW**

### **PATENT LAW**

30. Patents are private rights, for which the relevant domestic law provides a mechanism of enforcement through private remedies; specifically, in the context of patents, Section 55 of the *Industrial Property Act* (No. 3 of 2001) provides for enforcement of rights of patent holders. Pursuant to this section, the complainant has the burden of establishing that the alleged infringer had actual knowledge that he was using the protected matter, and that written notice was provided to the infringer, before any remedy is available (including injunction, damages and compensation). Furthermore, the *Industrial Property Act* does not presume validity of patents, and includes provisions that allow for patents to be invalidated or revoked.
31. The *Anti-Counterfeiting Act* apparently circumvents this procedure, allowing for seizure and detention of goods suspected to be counterfeit goods; under the Act, border guards would be empowered to seize and detain generic medicines which are suspected to fall within the Act. This is contrary to Article 44 of the TRIPS agreement which allows countries to limit enforcement measures to “declaratory judgments and adequate compensation” after a full judicial proceeding.
32. Additionally, under the *Anti-Counterfeit Act*, the onus is upon the person from whom the goods are seized to seek a declaration that the goods are not counterfeit goods, and to seek their return. This could prove to be an onerous requirement that is difficult to comply with, further curtailing access to necessary medicines guaranteed under the right to health.
33. Further, the *Anti-Counterfeit Act* seeks to utilise the scarce financial resources of the State and the mechanism of state agencies under various laws to protect and implement the rights of commercial entities, for which protection mechanisms under private law already exist. It is submitted that further protection of these rights is unnecessary, and thus constitutes an unjustifiable restriction on the right to health.
34. It is clear that enforcement of private rights by State agencies, via criminal sanctions imposed by anti-counterfeiting legislation, is impermissible under patent law.

## **PARALLEL IMPORTATION**

35. The *Anti-Counterfeit Act* seeks to expand the scope of rights of the owner of intellectual property rights, especially patents, beyond those granted by existing laws through other methods. For example, section 58(2) of the *Industrial Property Act* (No. 3 of 2001) limits the rights of a patent holder and statutorily recognises the mechanism of parallel importation by utilising the flexibility available under Article 6 of the TRIPS Agreement with respect to exhaustion of rights. It provides that the rights 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”.

36. Despite the proviso within the definition of “counterfeiting” under the Act (namely, that nothing in the paragraph shall derogate from the existing provisions under the *Industrial Property Act*), it is submitted that the *Anti-Counterfeit Act* is likely to affect the import, sale and distribution of generic medicines through parallel importation. This is likely to have a serious impact on the right to health, more specifically the right to access medicines, of the citizens of the Republic of Kenya and other persons within the territory of the Republic of Kenya (should the Act be considered to apply extraterritorially).

### **EXTRA-TERRITORIAL APPLICATION OF THE ACT**

37. It is well established that intellectual property rights are territorial in nature, but the Anti-Counterfeit Act purports to have extraterritorial application in providing protection to intellectual property rights existing outside the Republic of Kenya. “Counterfeiting” is defined as including “taking the following actions without the authority of the owner of intellectual property rights subsisting **in Kenya or elsewhere** in respect of protected goods...” (emphasis added).
38. As such, the Act is exceptionally broad, being that it has application in respect to non-Kenyan citizens and relevant acts committed outside the territory and jurisdiction of the Republic of Kenya. This extraterritorial application of the law will also result in the seizure of goods in international territorial waters and non-customs territories. This is unprecedented in patent law.
39. Extraterritorial application of private national laws has been heavily criticised, particularly on the grounds that undermines a fundamental principle of international law: namely, the respect between nations of the existence and integrity of national sovereignty, by allowing one State to effectively interfere in the affairs of another State. It is one thing to impose national laws on citizens of another country whilst they are in the State’s jurisdiction, or, equally, to impose national laws on one’s own citizens whilst they are abroad. However, imposition of national laws on foreigners outside the Kenyan jurisdiction may result in legal complexity and costly systems, at best, and may additionally prove antagonistic and difficult to enforce.

### **CONCLUSION**

40. **THAT** enforcement of the *Anti-Counterfeit Act* (No. 13 of 2008) will infringe the rights of Kenyan citizens living with HIV and AIDS; specifically, under the Constitution of the Republic of Kenya, as enumerated in Articles 26(1) and 43, for the following reasons:

- a. Generic medications used in combination therapy for HIV/AIDS are likely to be deemed counterfeit under the Act and therefore liable to be seized and detained;
- b. As such, enactment and enforcement of the Act will limit access to affordable generic medicines used to treat HIV/AIDS and associated opportunistic infections;
- c. Accordingly, the cost of obtaining antiretrovirals will increase significantly, and those suffering from HIV/AIDS will be compelled to access expensive, branded medicines;
- d. A number of individuals will effectively be unable to access medicines to manage their HIV/AIDS appropriately, and this will constitute a threat to the Constitutional right to life guaranteed in the Republic of Kenya.

**41. THAT** the Act, as it stands, contains an ambiguous definition of “counterfeiting” that if misinterpreted would impact adversely on the right to life enshrined in the Kenyan Constitution; specifically, through the definition potentially conflating issues of intellectual property rights and quality control.

**42. THAT** the Act purports to impose criminal sanctions in respect of patent rights already enforceable through private law mechanisms, and as such represents an unnecessary legislative overlay which potentially curtails or restricts the right to life as enshrined in Sections 26 and 43 of the Constitution.

**43. THAT** the Act may override other legislation which specifically provides rights for the petitioners to access essential medications, namely:

- a. Provisions of the *HIV and AIDS Prevention and Control Act* (No. 14 of 2006), particularly Section 3, which ensures the full protection of the human rights of those infected with HIV and AIDs through, inter alia, provision of basic health care for those persons; and
- b. Through failure to clarify with sufficient precision that the provisions of the *Industrial Property Act* (No. 3 of 2001), particularly those Sections relating to parallel importation of medicines, will continue to apply to ensure generic drugs are available in Kenya.

**44. THAT** the Act purports to have extra-territorial application, which is unprecedented in the sphere of patent law, and is so broadly drafted that it may prove to be unenforceable, inter alia, in respect of its purported application to foreign nationals;

**45. THAT** this application be considered as a matter of urgency by this Honourable Court, as the petitioners’ constitutional rights, especially the right to life as enumerated in Sections 26 and 43, are under direct threat;

**46. THAT** as the Sections of the Act in question have not yet commenced, there cannot be said to be any prejudice arising from a order staying commencement of the same;

**47. THAT** the Respondent will not suffer any prejudice whatsoever by the introduction of Mr Anand Grover as an interested party.

**48. THAT** I do swear this affidavit in support of the application, and do so conscientiously believing it to be true within my knowledge, save for matters and information and belief sources whereof have been respectively disclosed.

**SWORN** by **ANAND GROVER** ]  
the United Nations Special ]  
Rapporteur on the Right of Everyone ]  
to the Enjoyment of the Highest ]  
Attainable Standard of Physical and ]  
Mental Health ]  
] ]  
**ANAND GROVER** ] **DEPONENT**  
] ]  
At Mumbai, India, ] ]  
] ]  
this day of 2010 ] ]  
] ]  
] ]  
BEFORE ME: ] ]  
] ]  
] ]  
] ]