PATENTING THE UN-PATENTABLE: LESSONS FOR AFRICAN PATENT SYSTEMS FROM A REVIEW OF PATENT SUBJECT MATTER EXCLUSIONS IN KENYA

VICTOR NZOMO*
Ph.D. Candidate and Research Fellow, Centre for Intellectual Property and Information Technology Law, Strathmore University Law School, Kenya

ISAAC RUTENBERG**
Senior Lecturer and Director, Centre for Intellectual Property and Information Technology Law, Strathmore University Law School, Kenya

ABSTRACT

On 9th February 1994, Kenya Industrial Property Office (now known as Kenya Industrial Property Institute – KIPI) granted Kenya's first patent under the post-independence patent system. This patent was for a protein derived from tick larvae suitable for the protection of grazing cattle from ticks. It appears that this patent was granted with claims to a method for treating animals, despite an express statutory exclusion from patentability of such inventions.

The patent system is built on a trade-off whereby, in exchange for a limited monopoly over a fixed period, an inventor discloses the knowledge embodied in an invention to the State in trust for the public. Key to this assumption is that society has a system in place in which experts in the respective fields to which the inventions pertain have the capacity to evaluate the merits of the claimed inventions in terms of statutory requirements, including subject matter eligibility. By limiting subject matter eligibility within the patent statutes, societal burdens stemming from grants of patent rights are minimized in targeted areas. This trade-off implicitly assumes the availability of granted patents tabulated in a substantive database of eligible patent subject matter. Deviations from such expectations risk the patent system becoming a rip-off rather than a trade-off.

Proceeding from this initial premise, this article examines the origins of the subject matter categories excluded from patent protection from the 1624 Statute of Monopolies to the present day. Using Kenya as a case study, this article offers a preliminary review of patent data showing the number of patents having claims directed to subject matter excluded from patent protection in the operative law. It is hoped that the research described in this article will be of use to other African countries wishing to strengthen the value and effectiveness of their respective patent systems in the public interest.

Key words: invention, patentable subject matter, patents, patent offices, patent law, Kenya, Africa

Electronic copy available at: https://ssrn.com/abstract=3012135

1. INTRODUCTION

Patents are sometimes regarded as indicative of the pinnacle of innovation or a symbol of genius.[1] Indeed this positioning of patents at the top of the intellectual property (IP) hierarchy likely stems from the relatively strict and technical examination process that is often necessary to obtain a granted patent.[2] The patent examination process typically includes the evaluation of a number of substantive criteria. This work focuses on one of the threshold requirements for a grant of patent, namely subject matter eligibility.

Recent statistics by the World Intellectual Property Organization (WIPO) on total (resident and abroad) patent filing activity by origin indicate that Kenya is ranked 1st among member states of African Regional Intellectual Property Organization (ARIPO) and 7th on the African continent, behind Tunisia, Senegal, Cameroon, Morocco, Egypt and South Africa respectively.[3] Patents in Kenya are regulated by the Industrial Property Act 2001 (IPA 01)[4] and the IPA Regulations of 2002.[5] Section 3 of the IPA establishes the Kenya Industrial Property Institute (KIPI, i.e., the Kenyan patent and trademark office) whose primary function to consider applications for and grant industrial property rights is contained in section 5 of the IPA. There is a two-step criteria for determining patent subject matter eligibility under the IPA and both steps must be satisfied. First, the subject matter contained in the patent application must not be directed to one of the five statutory categories of non-inventions, and second, the claimed invention must not be directed to one of the two statutory categories of non-patentable inventions, as discussed below.

One rationale given for the patent system in Kenya originates from utilitarianism: without the possibility of patent protection, many people might not risk the time and money involved in devising and perfecting new products.[6] Therefore the theoretical assumption underpinning the patent system is that in exchange for a limited monopoly over a fixed period, an inventor discloses the knowledge embodied in an invention to the State in trust for the public.[7] This exchange requires two key functions: a gatekeeping function, and an information function. The gatekeeping function means that the state-operated patent administrative system employs experts in the respective fields to which the various inventions pertain, those experts having the capacity to evaluate the merits of the claimed inventions in terms of subject matter eligibility and other

---

* LL.B (UNISA), LL.M (UON), Ph.D Candidate, Commercial Law Department, Faculty of Law, University of Cape Town, South Africa. This work is not related to, neither does it form part of, the PhD research of the author.
** BSc (CSM), Ph.D (CIT), J.D (SCU). Corresponding author (email: irutenberg@strathmore.edu). The views expressed as well as any errors in the work are solely those of the authors.

[1] B Sihanya *Intellectual property and innovation law in Kenya and Africa: Transferring technology for sustainable development* (2016) 84.
[2] L Bently and B Sherman (eds) *Intellectual property* 4th ed (2014) 375.
[3] World Intellectual Property Organization (WIPO) 'World intellectual property indicators 2016', available at http://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2016.pdf (accessed on February 20, 2017).
[4] Industrial Property Act, Republic of Kenya, 2001.
[5] Industrial Property (Act) Regulations, Republic of Kenya, 2002.
[6] Kenya Industrial Property Office, 1994, p. 1.
[7] J de Beer, C Armstrong, C Oguamanam & T Schonwetter (eds) *Innovation & intellectual property: Collaborative dynamics in Africa* (2014) 234.

Electronic copy available at: https://ssrn.com/abstract=3012135

substantive requirements for grant of patents.[8] Patent examiners at the patent office carry out this function. The information function means that the patent system in Kenya facilitates knowledge sharing by making available to the public patent information that is vital for entrepreneurs, researchers, inventors, academics and others who need to keep up with development in their fields.[9] A compliant patent application with sufficient disclosure and description carries out this function, particularly as patent applications and granted patents are published by the patent office and available for public inspection.

This work posits that the beneficial trade-off suggested by utilitarian theory requires a patent system to effectively implement the gatekeeping and information functions with respect to patentable subject matter. Thus, the central question of the research described in this article is whether the patent system in Kenya is adequately executing its gate-keeper and information functions by ensuring that patents are not granted for non-inventions and non-patentable inventions. To determine this question, we analyze the extent to which the statutory restrictions on patentable subject matter comport with the reality of granted patents in Kenya.

Following this introduction, the next section of this article explores the development of the law on patentable subject matter in Kenya. Sections 3, 4 and 5 present and evaluate data from Kenya's patent records, with respect to patents granted having claims directed to non-inventions and non-patentable subject matter. Section 6 offers our conclusions and recommendations for African patent offices, based on the findings from both the legal doctrinal data and the patent applications data in Kenya, in respect of patent subject matter eligibility.

2. PATENTABLE SUBJECT MATTER IN KENYA

a. Historical development of patentable subject matter in Kenyan law

The development of patent law in Kenya can be divided into three time periods: (a) 1913 to 1989, (b) 1989 to 2001, and (c) 2001 to present day.[10] Between 1913 and 1989, patentability in Kenya was regulated by the patent system of the United Kingdom (U.K.) which stipulated that patents in Kenya were governed by the patent law of the U.K.[11] Pursuant to the U.K Patents and Designs Ordinance 1913, the first patent in Kenya was registered on 23 December 1914 in the name of Marconi's Wireless Telegraph Company Limited (UK).[12]

---

[8] J de Beer, C Armstrong, C Oguamanam & T Schonwetter (eds) *Innovation & intellectual property: Collaborative dynamics in Africa* (2014) 234.
[9] Kenya Industrial Property Office *Guide to patenting in Kenya* (1994) 1.
[10] D Njuguna 'The role of national IP offices: Kenya' available at http://www.wipo.int/edocs/mdocs/africa/en/wipo_id_hre_15/wipo_id_hre_15_t_3b.pdf (viewed on 20 February 2017).
[11] JO Otieno 'The Kenya patent law: Promoting local inventiveness or protecting foreign patentees?' (1994) 38 *Journal of African Law* 79.
[12] Government Press *The official gazette of the East Africa protectorate* (1914) 1265.

Therefore in Kenya's pre-1989 era, to obtain patent protection, an applicant was required to present a certified copy of letters patent from the U.K. Patents Office and the U.K. patent was subsequently re-registered in Kenya without further examination.[13] Accordingly, the patents granted in Kenya were dependent upon patent grant in the U.K. and the rights conferred to the Kenyan patentee were rights existing in the U.K. patent law.[14] The rationale for a dependent patent system was that the Kenyan Patent Office was inadequately equipped to substantively examine patent applications.[15]

Between 1913 and 1989, the sources of law on patentable subject matter in Kenya were the UK Patents Act 1949 and the UK Patents Act 1977 (UKPA 77). Up until 1977, patent subject matter eligibility in Britain required that the claimed invention was a 'manner of new manufacture', a phrase that was first used in the 1624 Statute of Monopolies.[16] As such, the most important source of law on patentable subject matter in Kenya's pre-1989 era was UKPA 77. The UKPA 77, which established the UK Patent Office (now known as the UK Intellectual Property Office) is the substantive law of patents in the UK and was introduced to implement the European Patent Convention 1973 (EPC 73).[17]

With regard to patentable subject matter, section 1 of UKPA 77 stated as follows:

> 1 Patentable inventions.
>
> (1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say—
>
> (a) the invention is new;
>
> (b) it involves an inventive step;
>
> (c) it is capable of industrial application;
>
> (d) the grant of a patent for it is not excluded by subsections (2) and (3) below;
>
> and references in this Act to a patentable invention shall be construed accordingly.
>
> (2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of—
>
> (a) a discovery, scientific theory or mathematical method;
>
> (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
>
> (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
>
> (d) the presentation of information;

[13] JO Otieno 'The Kenya patent law: Promoting local inventiveness or protecting foreign patentees?' (1994) 38 (2) *Journal of African Law* 79.
[14] C Juma & JB Ojwang (eds) *Innovation and sovereignty: The patent debate in African development* (1989) 214
[15] JO Otieno 'The Kenya patent law: Promoting local inventiveness or protecting foreign patentees?' (1994) 38 (2) *Journal of African Law* 79.
[16] L Bently & B Sherman (eds) *Intellectual property* 4th ed (2014) 453.
[17] T Aplin & J Davis (eds) *Intellectual property law: Text, cases and materials* 3rd ed (2017) 629.

> *but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.* [Emphasis ours]

This section is almost identical to section 52 of EPC 73. It is significant to note that the above emphasized 'as such' provision of section 1(2) of UKPA 77 and section 52(3) of EPC (3) clearly distinguishes between instances where excluded subject matter is used in ways that produce no technical result on one hand and instances where excluded subject matter is used in a technical process and provide as its result a certain change, on the other hand. The latter subject matter is eligible for patent protection.[18] In other words the effect of the "as such" exclusion is not, therefore, to prevent any of the categories mentioned in it from constituting an integral part of a comprehensive patentable invention, it merely entails that the listed classes of mental products themselves do not qualify as patentable inventions.

In 1989, the first independent patent system was introduced in Kenya through the Industrial Property Act of 1989 (IPA 89). The features of Kenya's new postcolonial patent system included the establishment of the Kenya Industrial Property Office and the Industrial Property Tribunal with the latter having powers to invalidate patents over claimed inventions that are not patentable or that are excluded from protection. Sections 6 and 11 of IPA 89 dealt with patent subject matter eligibility as follows:

> Part III
> Patentability
> Meaning of "Invention"
> 6. (1) For the purposes of this Part, "invention" means a solution to a specific problem in the field of technology.
> (2) Subject to subsection (3), an invention may be, or may relate to, a product or a process.
> (3) The following shall not be regarded as inventions for the purposes of patent protection—
>
> (a) discoveries or findings that are products or processes of nature where mankind has not participated in their creation (including animals, plants and microorganisms) and scientific and mathematical methods and theories;
> (b) schemes, rules or methods for doing business, performing purely mental acts or playing games, and computer programmes;
> (c) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods; except products, in particular substances or compositions, for use in any of those methods; or
> (d) mere presentation of information. [Our emphasis]
>
> (...)
> Non-Patentable Inventions
> 11. The following shall not be patentable—

[18] VICOM, 1987, para.79

> (a) plant varieties as provided for in the Seeds and Plant Varieties Act, but not parts thereof or products of biotechnological processes;
> (b) inventions contrary to public order, morality, public health and safety, principles of humanity, and environmental conservation; and
> (c) any other inventions that may be declared non-patentable by the Minister.

On the face of it, IPA 89 marked a significant departure from PA 77 in terms of patent subject matter eligibility since it introduces the two step criteria for determining patent subject matter eligibility in sections 6 and 11 as reproduced above. These provisions were not substantially affected by subsequent revisions to IPA 89. It has been argued that the 'as such' exclusion in UKPA 77 may be equated to use of the words 'mere' with regard to excluded subject matter categories.[19]

Section 6(3)(c) of IPA 89 introduces a new category of excluded subject matter namely methods of medical and veterinary treatment. This exclusion is confined to methods for treating humans and animals, and therefore does not prevent patents directed at surgical, therapeutic, or diagnostic substances, compositions (such as drugs), apparatuses, or other products. This provision is almost identical to section 52(4) of EPC 73 that states that this category of subject matter is not regarded as an invention and thus excluded from patentability on the basis that it is not susceptible of industrial application. It is reasoned that this bar to patentability was introduced for ethical reasons to prevent the monopolisation of medical and veterinary techniques that require the positive action of a person for their application.[20]

Additionally, section 11 of IPA 89 introduces patent subject matter exclusion for two types of inventions namely '(a) plant varieties as provided for in the Seeds and Plant Varieties Act, but not parts thereof or products of biotechnological processes'; and '(b) inventions contrary to public order, morality, public health and safety, principles of humanity, and environmental conservation.' The origin of the exclusion in section 11(a), which may have been borrowed from Article 53(b) of EPC 73, may be explained in light of the sui generis plant breeder's protection established in the International Union for the Protection of New Varieties of Plants 1961 (UPOV 61). Kenya enacted the Seeds and Plant Varieties Act in 1972, becoming the first country in Africa to introduce plant variety protection. Thus, the exclusion in IPA 89 prevents plant breeders from obtaining dual protection under both plant breeder's legislation and patent law.[21]

By the late 1990s, Kenya had joined WIPO, ARIPO, World Trade Organization (WTO) and International Union for the Protection of New Varieties of Plants (UPOV), and was therefore required to conform its national law on patent subject matter eligibility with the provisions of

[19] EA Crowne-Mohammed 'A review of the "as such" exclusions to patentable subject matter in the United Kingdom: Lessons for Canadian and American courts' (2010) 20(3) *Albany Law Journal of Science and Technology* 467.
[20] A van der Merwe, H Klopper, T Pistorius, B Rutherford, LA Tong & P van der Spuy (eds) *Law of intellectual property in South Africa* (2011) 291.
[21] T Aplin & J Davis (eds) *Intellectual property law: Text, cases and materials* 3rd ed (2017) 676.

Paris Convention for the Protection of Industrial Property, Harare Protocol on Patents and Industrial Designs (Harare Protocol), Patent Cooperation Treaty, WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and UPOV 78. The TRIPS Agreement, in Article 27.2 and 27.3, provides specific categories of subject matter that the WTO Members are entitled to exclude from patentability. Similarly, Article 10(h), (i) and (j) of the Harare Protocol sets out subject matter excluded from patentability as well as a list of non-patentable inventions.

b. Patentable subject matter under the current legal regime in Kenya

In 2001, Kenya repealed IPA 89 and passed IPA 01 in order to comply with its various international treaty obligations, notably TRIPS. The IPA 01 authorizes KIPI to maintain a corps of examiners with the scientific and legal expertise necessary for carrying out substantive examination of patent applications. Today, KIPI is one of the most active patent offices on the continent, and also one of the only national offices to carry out substantive (as opposed to formalities) examination of patent applications.[22]

The IPA 01 (in Section 22) provides substantive requirements for patentability: novelty, inventive step, and industry applicability. In addition to these requirements, Sections 21(3) and 26(a) and (b) of IPA 01 contain an exhaustive list of subject matter categories that are *ineligible* for patent protection. The section reads thus:

> 21.
>
> 3) The following shall not be regarded as inventions and shall be excluded from patent protection:
>
> (a) discoveries, scientific theories and mathematical methods;
>
> (b) schemes, rules or methods for doing business, performing purely mental acts or playing games;
>
> (c) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practised in relation thereto, except products for use in any such methods;
>
> (d) mere presentation of information; and
>
> (e) Public Health related methods of use or uses of any molecule or other substances 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. [Our emphasis]
>
> 26. The following shall not be patentable: -
>
> (a) plant varieties as provided for in the Seeds and Plant Varieties Act, but not parts thereof or products of biotechnological process; and

[22] Most patent offices in Africa, including national offices in Nigeria and South Africa, and including the regional office of the Organisation Africaine de la Propriété Intellectuelle (OAPI), merely register patent applications after a formalities examination.

> (b) inventions contrary to public order, morality, public health and safety, principles of humanity and environmental conservation.

It is worth noting that IPA 89 included an identical list but for one additional item: computer programs. The removal of computer programs from the list in the IPA 01 implies that such inventions are were made patentable with the adoption of the new law.[23] A caveat to this conclusion is that computer software claims must not be directed to methods of doing business, as such subject matter is still excluded by s. 21(3)(b) of IPA 01. In Kenya, as discussed below, KIPI has granted some patents with claims directed at computer programs. The Industrial Property Tribunal and the courts are yet to weigh in on the debate as to whether such software patents should be enforceable.[24]

c. Methodology

In Part 3 of this article below, we provide evidence and analysis showing that claims directed to several of the categories of non-inventions or non-patentable subject matter can be found in duly examined and granted Kenyan patents. In making such determinations, we evaluated the granted claims of approximately 400 Kenyan patents numbered between KE1 and KE711. We obtained such claims directly from KIPI in the form of digital image files.[25]

3. EXCLUDED PATENT SUBJECT MATTER IN KENYA

a. Non-inventions present in granted patents

The first type of patent subject matter ineligibility in IPA 01 relates to creations that are deemed not to be inventions. Data collected on granted patents in Kenya shows, as described below, that KIPI has granted patents directed at non-inventions.

In particular, and despite the prohibition against patenting methods for treatment of the human or animal body, we identified a number of granted patents with claims directed at such subject matter. Our searches revealed patents with claims that fall into three categories: claims that explicitly state a method of treating a patient; claims that are implicitly drawn to a method of

[23] B Sihanya *Intellectual property and innovation law in Kenya and Africa: Transferring technology for sustainable development* (2016) 101.

[24] V Nzomo 'Should Kenya allow software patents?', available at http://blog.cipit.org/2012/08/15/should-kenya-allow-software-patents/ (viewed on February 20, 2017).

[25] To the best of our ability we were not able to find *granted* claims in publicly available online patent databases. The databases that we searched (e.g., Patentscope from WIPO, eSpaceNet from the EPO, etc.) contain Kenyan patent application publications but not granted claims. Accordingly, all claims analysed herein were obtained directly from KIPI, either via personal inspection of KIPI's physical files, or via electronic communication with KIPI officials. We have discounted the possibility of any post-grant amendment of the patent claims, as the Industrial Property Act 2001 contains no provision for post-grant amendment. Our analysis clearly assumes that the data in our possession is an accurate reflection of the granted and currently existing patent claims. For purposes of transparency, therefore, the raw data used for our patent claim analyses are available via links provided.

treating a human; and claims that are alternatively worded such that their compliance with Section 21(3) of IPA 01 is questionable. It should be noted at the outset that Kenyan courts have yet to offer any guidance on interpretation of these claims vis-à-vis excluded subject matter in IPA 01. Accordingly, throughout the following discussion, we cite to European jurisprudence as the most likely and relevant source for interpretation.[26]

In the first case, the claims are explicit, and specifically state treating a patient or administering a pharmaceutical compound. For example, KE 437[27] includes the following claim:

> 9. A method for the treatment or prevention of a disease or disorder linked to a dysfunction of peripheral-type benzodiazepine receptors, which comprises administering to a patient in need of such treatment or prevention a therapeutically effective amount of the crystalline form according to [an earlier claim].

It is difficult to argue that such a claim does not violate Section 21 of the IPA 01. In the European context, the Technical Board of Appeal has stated "the concept of 'therapy' or 'therapeutic application' includes treatment of a particular illness or disease with a specified chemical substance or composition in a specified human or animal subject in need of such treatment."[28] Where a claim lacks such specifics, it does not qualify as a therapy and cannot fall into the excluded subject matter of treating a human or animal. In the case of claim 9 of KE 437 shown above, these specific requirements appear to be present.

In the second case, the claims are implicit, and state a method for treating a disease without mentioning a human body. For example, Patent KE 691[29] includes the following claim:

> 6. Use of the aqueous product of [an earlier claim] for treatment and management of diabetes, HIV, Cancer, arthritis, menstrual discomforts, infertility, fibroid among other diseases.

Such a claim falls short of providing the full details required by the Technical Board of Appeal To some extent it is possible to interpret these claims as drawn to *in vitro* treatments (i.e., in laboratories) rather than *in vivo* treatments (i.e., in the body), and indeed some few of these

[26] The European Patent Convention, Article 52(4), is similar but not identical to Section 21(3) of the IPA 01. It reads, in full: "Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods." The European law, therefore, anchors the non-invention status of therapeutic methods to a lack of industrial applicability, whereas the Kenyan law is silent as to why therapeutic methods are non-inventions.

[27] Patent Number KE 437, 'Novel Crystalline Form of a Pyridazino [4,5-B] Indole Derivative' available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-437.pdf (viewed on September 20, 2017).

[28] *Sequus Pharmaceuticals*. T 4/98 [2002] *OJ EPO* 103, at paragraph 8.

[29] Patent Number KE 691, 'Hyssop (Capparis Tomentosa) Medicinal Product Used in Management of Chronic Diseases' available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-691.pdf (viewed on September 20, 2017).

claims from various patents specify *in vitro* treatment.[30] Nevertheless *in vitro* treatment methods are typically of little use in the practical treatment of patients, and it is unlikely that such patents were intended by the applicant/owner to be so limited. Alternatively, it could be argued that the claims are merely directed to treating a disease, and that such diseases are not limited to affecting humans and animals.[31] On balance, this second type of claim is highly suspect as violating Section 21(3) of IPA 01.

In the third case, a variety of alternative phrasings were found that are not dispositive but raise questions of compliance with IPA 01. An example is a use-type claim that implicitly treats a human by use of a device. For example claim 5 of KE 338[32] reads as follows:

> 5. The use of the mechanism according to [a previous claim] or a device according to [a previous claim] for the administration of a pharmaceutical formulation to the human or animal body.

Such a claim is directed to the use of a mechanism, although it is unclear whether inclusion of the phrase "for the administration of a pharmaceutical formulation to a human" necessarily means that this claim is directed to a method of therapeutic treatment of a human. Infringement of the claim may require an active step involving treating a human, although even in such a case, issues of infringement may not be considered relevant when deciding patentability. A second example of this class of claims is a claim directed to a dosage scheme, such as claim 12 of KE 329,[33] which reads as follows:

> 12. Dosage scheme for the treatment of leishmaniasis in humans by oral administration of the solid pharmaceutical compositions according to [a previous claim], characterized in that a total daily dosage in the range of 10 to 250 mg a.i. miltefosine is administered orally over a period of time of 2 to 6 weeks.

In the European context, claims to dosage schemes are generally allowable provided that they are written in an acceptable format.[34] As noted above, inclusion of specific details such as the condition to be treated, the compound to be administered, and the identity of the patient may cause a claim to be construed as a therapy, and therefore excluded subject matter. Such details are provided in claim 12 of KE 329. On balance, this third type of claim is subject to interpretation and therefore could be found compliant or non-compliant.

---

[30] L Bently & B Sherman (eds) *Intellectual property* 4th ed (2014) 450: 'The exclusion of methods of medical or veterinary treatment only applies to methods of treatment that are practised on or in the human or animal body.'
[31] See for example, *Salimen/Pigs III*, T 58/87 [1989] EPOR 125; *Siemens/Flow measurement*, T254/87 [1989] *OJ EPO* 170.
[32] Patent Number KE 338, 'Dose Display Mechanism for a Drug Delivery Device' available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-338.pdf (viewed on September 20, 2017).
[33] Patent Number KE 329, 'Solid Pharmaceutical Compositions Containing Miltefosine for Oral Administration in the Treatment of Leishmaniasis' available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-329.pdf (viewed on September 20, 2017).
[34] See for example, *Abbott Respiratory/Dosage Regime*. G 2/08 [2010]

Table 1 provides a summary of seemingly non-compliant and questionable claims, as well as further example claims from a broader selection of patents having grant dates that range from 1994 through 2016. These claims are either explicit or implicit in stating a method of treating a human body.

Table 1. Example patents containing claims directed to treatment of a human

Patent No.	**Title**	**Claim Examples**
KE 711[35] Granted 14/03/16	INHIBITORS OF NEDD8-ACTIVATING ENZYME	32. Use of the chemical entity of any of one of [earlier claims] for the treatment of cancer. 34. Use of the chemical entity of any of one of [earlier claims] for the treatment of inflammatory disorders, inflammation associated with infection, neurodegenerative disorders, ischemic injury, or cachexia.
KE 691 Granted 11/06/15	HYSSOP (CAPPARIS TOMENTOSA) MEDICINAL PRODUCT USED IN MANAGEMENT OF CHRONIC DISEASES	6. Use of the aqueous product of [earlier claims] for treatment and management of diabetes, HIV, Cancer, arthritis, menstrual discomforts, infertility, fibroid among other diseases.
KE 552[36] Granted 13/09/12	MEDICINAL AND HERBAL COMPOSITION AND USES THEREOF	12. Use of a pharmaceutical composition [as in an earlier claim] to treat HIV/AIDS, herpes, Kaposi's sarcoma, or an autoimmune disease.
KE 437 Granted 26/04/11	NOVEL CRYSTALLINE FORM OF A PYRIDAZINO [4,5-B] INDOLE DERIVATIVE	9. A method for the treatment or prevention of a disease or disorder linked to a dysfunction of peripheral-type benzodiazepine receptors, which comprises administering to a patient in need of such treatment or prevention a therapeutically effective amount of the crystalline form according to [an earlier claim].
KE 208[37]	2-(3,5- BIS-TRIFLUOROMETHYL-	7. The use of the compound of [a previous claim] for the treatment of diseases.

[35] Patent Number KE 711, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-711.pdf (viewed on September 20, 2017).
[36] Patent Number KE 552, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-552.pdf (viewed on September 20, 2017).
[37] Patent Number KE 208, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-208.pdf (viewed on September 20, 2017).

Granted 13/10/05	PHENVL)- N-METHVL- N-(6-MORPHOLIN-4-YL-4-O-TOLYL- PYRIDIN3-YL)-ISOBUTYRAMIDE	
KE 168[38] Granted 13/01/03	ERYTHROPOITEIN	13. A method of treating a hematopoietic disorder comprising administering a therapeutically effective preparation of [an earlier claim].
KE 36[39] Granted 21/04/98	N,N'-BIS(QUINOLIN-4-YL)-DIAMINE DERIVATIVES, THEIR PREPARATION AND THEIR USE AS ANTIMALARIALS	10. The use of compounds according to [an earlier claim] in the treatment or prevention of illnesses.
KE 1[40] Granted 09/02/94	NOVEL TICK RESISTANCE ANTIGENIC INDICATORS (TRAI) FOR HOST ANIMALS	21. A method for the control of tick infestation of a warm-blooded animal which comprises immunizing the animal with an antigenic composition or a vaccine according to [an earlier claim].

Characterization of methods of treating a human body as non-inventions is not unique to Kenya, but is found in many jurisdictions worldwide, including in the European Patent Office. In such jurisdictions, it is standard practice to use alternative wording in medicinal claims, namely, second medical use claims (also known as "Swiss Style" claims). Such claims are phrased as methods for the preparation of a medicament, the medicament being useful in treating a human body for one or more conditions. Second medical use claims are common in Kenyan granted patents, but alongside such claims can also be found a substantial number of claims (as demonstrated by Table 1 and other examples above) that expressly claim a method of treating a specific condition or a human having a specific condition.

b. Non-patentable subject matter present in granted patents

[38] Patent Number KE 168, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-168.pdf (viewed on September 20, 2017).
[39] Patent Number KE 36, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-36.pdf (viewed on September 20, 2017).
[40] Patent Number KE 01, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-01.pdf (viewed on September 20, 2017).

The second type of patent subject matter ineligibility in IPA 01 relates to inventions that are deemed non-patentable. These inventions fall into two categories: plant varieties but not parts thereof or products of biotechnological processes; and inventions contrary to public order and the like. Because the latter category is entirely subjective, we have chosen to focus on granted patents potentially containing claims to the former category. Table 2 contains representative claims from various granted Kenyan patents claiming plants and plant parts.

Table 2. Example patents containing claims to plants and plant parts

Patent No.	**Title**	**Claim Examples**
KE 447[41] Granted 17/06/11	ROSE CONTAINING FLAVONE AND MALVIDIN, AND METHOD FOR PRODUCTION THEREOF	1. A rose characterized by comprising a flavone and malvidin added by a genetic modification method. 2. A rose according to claim 1, which comprises a flavone and malvidin by expression of pansy (*Viola x wittrockiana*) flavonoid 3',5'-hydroxylase and anthocyaninmethyltransferase.
KE 325[42] Granted 30/06/09	PROCESS FOR PRODUCING ROSE WITH MODIFIED COLOUR	1. A rose obtained by the production method according to any one of claims 1 to 4, or a progeny or tissue thereof having the same properties as the rose.
KE 308[43] Granted 31/03/09	PLANT CULTIVATION METHOD	1. Young plant which is distinguished in particular by an increased branching rate, rapid growth, compact foliage, auto regulation of the plant, characterized in that it is obtained from a micro plantlet obtained from an explant, or derivative of an explant of the plant to be propagated, subject to the culture conditions of the method according to [an earlier claim].
KE 143[44] Granted 04/03/02	SELF-DEFOLIATING PLANT	1. A self-defoliating cotton plant. 2. A plant according to claim 1, wherein the cotton plant comprises a nucleic acid sequence or functional fragment thereof which is activated to effect self-defoliation of the cotton plant.

[41] Patent Number KE 447, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-447.pdf (viewed on September 20, 2017).
[42] Patent Number KE 325, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-325.pdf (viewed on September 20, 2017).
[43] Patent Number KE 308, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-308.pdf (viewed on September 20, 2017).
[44] Patent Number KE 143, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-143.pdf (viewed on September 20, 2017).

KE 104[45] Granted 07/07/02	PRODUCTION OF TREHALOSE IN PLANTS	1. A chimaeric plant expressible gene which when expressed in a plant or plant cell increases the trehalose content of said plant or plant cell.

At the outset, we note that the claims in Table 2 are directed to plants and/or to parts of plants (e.g., genes), rather than being directed to plant varieties. To the extent that the term "plant" is not equivalent to the term "plant variety", these claims would be compliant with the literal wording of Section 26(a) of the IPA 01.

There are currently no Kenyan court decisions addressing whether the terms "plant" and "plant variety" are equivalent. It is therefore not clear whether a Kenyan court would uphold the validity of claims directed to plants and parts of plants such as those in Table 2. Jurisprudence from the European Patent Office on this issue spans several decades and, on balance, supports the interpretation of these claims as patentable.[46]

In European jurisprudence, whether or not a plant is to be considered a plant variety depends only on whether or not it meets the criteria set out in the definition in Rule 23b(4) of EPC 73 which is now contained in Rule 26(4) of EPC 2000.[47] In the 1983 case of *Ciba Geigy*, the Board held that claims broadly directed to propagating material (e.g., seeds), wherein the material has been chemically treated, are valid.[48] The board recognized that the claims covered such chemical treatment as applied to propagating material from *all* plants (and therefore all plant varieties) that yield substances in any form. Nevertheless, the board allowed such claims, with the following reasoning:

> *"[T]he innovation claimed here does not lie within the sphere of plant breeding, which is concerned with the genetic modification of plants. Rather, it acts on the propagating material by means of chemical agents in order to make it resistant to agricultural chemicals. The new parameter for the propagating material, namely treatment with an oxime derivative, is not a criterion which can be characteristic of a plant variety as far as the protection of varieties is concerned. There is therefore no conflict between the protection of varieties or the patent as different forms of protection for propagating material treated in this way. In fact, patent protection is the only possibility. Technologically, the treatment with an oxime derivative is a plant protection measure which, in contrast to other cases, is carried out on a marketable object, namely the propagating material. It is not necessary for the object of the treatment always to be a plant variety, since the treatment can also be carried out on propagating material which does not meet the essential criteria of homogeneity or stability characteristic of a plant*

[45] Patent Number KE 104, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-104.pdf (viewed on September 20, 2017).
[46] European jurisprudence is relevant because Article 53(b) of the European Patent Convention is nearly identical to Section 26 of the IPA 01.
[47] *Consejo Superior/Oil from seeds*, T 1854/07 (12 May 2010)
[48] *Ciba-Geigy/Propagating material application*, T 49/83 [1979-85] C *EPOR* 758, [1984] *OJ EPO* 112.

> *variety. Conversely, it is immaterial to the question of patentability that the propagating material which is treated can also be, or is primarily, a plant variety.*[49]

An earlier case before the Enlarged Board of Appeal (EBA) posed the following question: "Does a claim which relates to plants but wherein specific plant varieties are not individually claimed ipso facto avoid the prohibition on patenting in Article 53(b) EPC even though it embraces plant varieties?" To this question, the EBA held that: "A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though it may embrace plant varieties."[50] Finally, in a more recent case, the EBA held that the exclusion of patentable subject matter for plant varieties "is restricted to very specific requirements and conditions that need to be fulfilled to justify the verdict 'unpatentable'."[51] The 'specific requirements' to which the EBA referred is the definition of "plant variety" as contained in Rule 26(4) EPC, which is substantively similar to the definition of "plant variety" in the Seeds and Plant Varieties Act 2012 in Kenya.

In view of the above, a Kenyan court following European jurisprudence would likely find claims such as those shown in Table 2 as not within the excluded non-patentable subject matter of Section 26(a).

c. Software patents

As noted above, Section 26 of the IPA 01 is nearly identical to the corresponding section of the previous law, IPA 89, with one notable exception: computer programs. With this change we contend that software became patentable subject matter in 2001. Data from KIPI support this conclusion, as described below.

We found at least a half dozen granted patents with software-type patent claims, including KE 300, KE 336, KE 596, and KE 599, among others. Selected claims from these patents are provided in Table 3. Software patent claims are in two varieties – claims specifically drawn to a computer program, such as claim 7 of KE 300, and claims drawn to a method that employs software, such as claim 1 in KE 599.

Table 3. Example Patents containing software-type claims

Patent No.	**Title**	**Claim Examples**
KE 300[52] Granted 12/02/09	METHOD, APPARATUS AND COMPUTER PROGRAM PROVIDING SIGNALLING OF	7. A program of machine-readable instructions, tangibly embodied on an information bearing medium and executable by a digital data processor, to perform actions directed toward providing a power control to a mobile station, the actions comprising: after scheduling a user equipment for an uplink packet transmission on a

[49] Id., at paragraph 4.
[50] *Novartis II/Transgenic plant*, G 1/98 OJ EPO 2000, 111.
[51] *State of Israel – Ministry of Agriculture*, G 2/12 (25 March 2015).
[52] Patent Number KE 300, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-300.pdf (viewed on September 20, 2017).

	ZERO/FULL POWER ALLOCATION FOR HIGH SPEED UPLINK PACKET ACCESS (HSUPA)	wireless data channel, accessing a data storage medium to determine a bit sequence that is associated with a zero power allocation; and transmitting to the user equipment a power control message for the scheduled uplink transmission that includes the determined bit sequence. 8. The program of claim 7, wherein the determined bit sequence comprises a first bit sequence, and wherein the data storage medium further comprises a second bit sequence associated with another power allocation relative to power on a channel other than the wireless data channel. 9. The program of claim 8, wherein each of the first and second bit sequences comprise E-DPDCHOPCCII power ratio signaling bits, and the other channel comprises the DPCCH.
KE 336[53] Granted 14/08/06	APPARATUS, METHOD AND COMPUTER PROGRAM PRODUCT TO MAINTAIN USER EQUIPMENT SERVING GRANT AT CELL CHANGE	11. A program of machine-readable instructions, tangibly embodied on an information-bearing medium and executable by a digital data processor, to perform actions directed toward establishing a Serving Grant (SG)… 12. The program of claim 11 wherein said receiving comprises receiving said information element•from a Radio Network Controller (RNC).
KE 596[54] Granted 02/08/13	METHOD, SERVER, MERCHANT DEVICE, COMPUTER PROGRAMS AND COMPUTER PROGRAM PRODUCTS FOR SETTING UP COMMUNICATION	14. A computer program comprising computer program code executable in a controller of a security server, wherein the computer program code, when run on the controller, causes the security server to perform the steps of: receiving a first message from a merchant device… 15. A computer program product comprising a computer program according to claim 14 and a computer readable means on which the computer program is stored.

[53] Patent Number KE 336, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-336.pdf (viewed on September 20, 2017).
[54] Patent Number KE 596, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-596.pdf (viewed on September 20, 2017).

KE 599[55] Granted 22/08/13	COMMUNICATIONS	1. A method in a communications system, comprising a step of sending a message from a mobile terminal to a radio access network on a common transport channel, wherein the message comprises information associated with one or more access entities of the radio access network, and the information which is sent to the radio access network is base on a default reporting configuration stored in the mobile terminal. 24. A computer program product comprising a set of instructions which when executed by a processor in a mobile terminal, causes the mobile terminal to send a message to a radio access network on a common transport channel, wherein the message comprises information associated with one or more access entities of the radio access network, the information being based on a default reporting configuration stored in the mobile terminal.

As stated previously, computer software claims appear to be valid under IPA 01, provided that such claims are not directed to methods of doing business. Our interpretation of the above claims places them safely within this proviso.

4. EVALUATION OF FINDINGS

From the findings above, the top violations or potential violations of patent subject matter eligibility relate to section 21(3)(c) of IPA 01. On the other hand, Section 21(3)(b) appears to be consistent with granted patents. Section 26(a) is consistent with granted patents assuming that Kenyan courts follow current European jurisprudence. Each of the categories will be discussed in turn.

With regard to the section 21(3)(c) violations, the claims identified herein relate primarily to human rather than veterinary treatment and treatment by therapy rather than surgery. According to the EPO, claims that are worded like: 'A method of treating dementia by administering a compound of formula X to a patient' such as KE 437 are excluded from patentability under Article 53(c) of EPC, as they should be excluded under the IPA 01.

[55] Patent Number KE 599, available at: http://blog.cipit.org/wp-content/uploads/2017/09/KE-599.pdf (viewed on September 20, 2017).

With regard to section 26(a), several granted patents contain claims to plants, and these potentially cover numerous plant varieties. The Enlarged Board of Appeal at the European Patent Office has held that such claims are not the same as claims to plant varieties, and are therefore not affected by patent law exclusions of plant varieties.

With regard to the section 21(3)(b), the various examples of software patents granted by KIPI suggest that at least in those instances the computer programs in question were not deemed to be methods for doing business or performing purely mental acts. The fact that claims specifically drawn to a computer program such as the example in KE 300 were not excluded from patentability suggests that, according to KIPI, a software providing a power control to a mobile station (for example) amounted to a 'technical effect' as per the approach taken in UK and at EPO. Similarly, for claims drawn to a method that employs software, such as claim 1 in KE 599, KIPI seems to take a permissive approach to the requirement that excluded subject matter must make a 'technical contribution' to the art in order to be patentable.

5. CONCLUSIONS AND RECOMMENDATIONS

From our analysis of the law and practice of patent subject matter eligibility, several conclusions can be drawn. First and foremost, it seems clear that a culture of invalidation and revocation proceedings is necessary in Kenya to ensure that only inventions that meet that meet the requisite subject matter threshold (as well as other statutory requirements) are conferred with patent protection. Second, the research findings suggest that a number of patents in Kenya are granted based on certain interpretations and approaches taken at KIPI that may be at odds with the established practice inherited from UK and Europe. We could find no Kenyan court cases exploring this topic, so we cannot comment on whether courts feel empowered to strike down patents with potentially un-patentable subject matter.

Where patent offices do not enforce subject matter exclusions in a coherent and consistent manner, this encourages questionable applications to be filed in the hopes that they will slip through and be awarded patent protection. Where such applications that violate subject matter exclusions are granted, this does a great disservice to the whole patent system and indeed the nation.

In general, patent offices are advised to provide users of the patent system with comprehensive guidelines that outline how patent examiners will construe and apply substantive provisions of patent law. In particular, there is a need for better specialized training of the users of the patent system to provide a check on the patent institutions within the system. In this regard, the evidence from this research points to a clear danger of patent offices taking the side of inventors over the public at large by granting patents with respect to non-inventions and non-patentable inventions.