

MODEL PROVISIONS TO PROMOTE

ACCESS

TO AFFORDABLE MEDICINES

IN THE INDUSTRIAL PROPERTY BILL 2009

SEPTEMBER 2012



CEHURD
social justice in health

WITH SUPPORT
FROM



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PROPERTY BILL 2009**

SEPTEMBER 2012

**CENTER FOR HEALTH HUMAN RIGHTS AND
DEVELOPMENT (CEHURD)**

WITH SUPPORT FROM UNDP UGANDA

TABLE OF CONTENTS

CONTEXT	4
PREAMBLE TO THE ACT	5
1. Interpretation	5
PART II—ADMINISTRATION	6
4. Functions of the registrar	6
5. Register of industrial property	7
PART III—PATENTABILITY	8
8. Product & process of “inventions” & exclusions from patentability	8
10. Novelty	9
11. Inventive step	10
16. Patents relating to micro-biological processes or products	12
PART V—APPLICATION, GRANT & REFUSAL OF GRANT OF PATENT	
21. Application for a patent	13
28. Filing date and examination of application as to form	15
31. Examination as to substance	16
32. Grant, registration, and publication and <u>post-grant opposition</u> of a patent	18
PART VI—INTERNATIONAL APPLICATIONS	20
35. Unsearched or unexamined international applications	20
PART VII— RIGHTS AND OBLIGATIONS OF THE APPLICANT OR THE OWNER OF THE INVENTION	21
38. Rights of the owner	21
39. Obligations of the owner	22
40. Remedies	23
43. Limitation of rights	24
44. Additional limited exception to exclusive rights	24
45. ARIPO Protocol on patents	25

PART X—CONTRACTUAL LICENCES	26
55. Prohibited terms in a licence contract	26
58. Compulsory licences for non-working and similar other reasons	27
59. Compulsory licences based upon interdependence of patents	30
60. Preconditions for grant of compulsory licences	31
61. Grant and terms of compulsory licences	32
62. Transfer of compulsory licence	34
63. Cancellation of compulsory licence	35
64. Registration of grant, cancellation or variation	36
PART XI— EXPLOITATION OF PATENTED INVENTIONS BY THE GOVERNMENT OR BY THIRD PARTIES AUTHORISED BY THE GOVERNMENT	37
66. Exploitation of patented inventions by the Government or by third parties authorized by the Government (Government use)...	37
PART XII—UTILITY MODELS	40
68. Applicability of provisions relating to patents	40
69. Special provisions relating to utility model certificates	40
PART XIII—INDUSTRIAL DESIGNS	41
71. Definition of an industrial design	41
PART XV—SURRENDER, REVOCATION AND INVALIDATION	42
90. Revocation or invalidation	42
91. Effect of revocation or invalidation	43
PART XVI—INFRINGEMENT	44
93. Remedies for utility models and industrial designs	44
96. Criminal proceedings	45
97. Presumption of use of patented process	46
99. Suspension of release by customs authorities	46
PART XVII— SPECIAL PROVISIONS ON ENFORCEMENT OF PATENT RIGHTS BY LICENSEES	47
102. Special provisions on enforcement of patent rights by licensees	47
PART XVIII—MISCELLANEOUS	48
110. Repeal of Cap. 216 and Cap. 218, transitional and savings provisions	48

CONTEXT

THE Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) sets the minimum standards that member countries have to meet in protecting intellectual property rights (IPRs). In the case of least developed countries (LDCs) such as Uganda, the Agreement provides for a degree of flexibility in fulfilling the minimum protection standards.

Uganda's Industrial Property Bill of 2009, is TRIPS-plus, that is, it unnecessarily goes over and above the minimum required standards in protecting inventions, trademarks, industrial designs and other forms of industrial property.

This extensive protection, coupled with the failure to utilise the flexibilities that the TRIPS Agreement offers LDCs, has negative implications for among other things, continued access to affordable medicines by Ugandans.

This booklet highlights, clause-by-clause, some of the adjustments that are needed in the bill in line with recommendations made by stakeholders at a consultative meeting held in March 2012. These recommendations were:

- TRIPS flexibilities for LDCs should be included.
- Provisions for criminal sanctions for IPR infringement should be deleted.
- Border measures relating to patents should be removed
- Competent authorities should be put in charge of the Bill/Act
- Adequate relief and remedies be provided for in place of criminal sanctions.

This work is also a synopsis of the model provisions drafted in August 2012 by a smaller group of stakeholders and experts who were supported by UNDP to draft model provisions addressing the above recommendations. This group consisted of 14 representatives of the Ministry of Justice and Constitutional Affairs; Ministry of Tourism, Trade and Industry; Uganda Registration Services Bureau; UNDP; CEHURD and legal experts.

PREAMBLE TO THE ACT

IN the Preamble of the Bill, an additional clause is proposed to explicitly state the deliberate attempt of the Bill to balance the rights of owners of industrial property with those of consumers of the resulting products. The language of the proposed additional clause is drawn from TRIPS [Article 7 & 8] which indicates the balance that should be in intellectual property (IP) legislation. The Act should also be designed to promote transfer of IP and dissemination of IP products.

An Act to provide for the promotion of inventive and innovative activities; to achieve a balance between the interests of inventors and innovators, users of industrial property, and social and economic welfare; to facilitate the acquisition of technology through the grant, transfer, dissemination, and regulation of patents, utility models, industrial designs and technovations and to provide for the designation of a registrar, to provide for the functions of the registrar, and the establishment of a register of industrial property rights and for related matters.

1. Interpretation

AN additional statement is proposed to the definition of “compulsory licence” because TRIPS standards require adequate remuneration of a right holder in lieu of exploitation of his/her patent. It should read:

“compulsory licence” means an authorization given by the competent authority to a person, firm or a private or state-owned or state-controlled entity, to exploit a patent, a utility model, a layout-design or an industrial design in Uganda without the approval of the rights owner, subject to the payment of adequate remuneration;

PART II—ADMINISTRATION

4. Functions of the registrar

TO this section, section 4(1)(d) should be added because patent applicants are required to file such information with their applicants according to another amendment to the Act. It thus reads:

(d) to provide an accessible database of product and/or process patents on pharmaceutical and micro-biological medicines, if and when granted, by reference to the required disclosure of international non-propriety name (INN) as soon as such name is assigned, or if such INN listing is not possible, by a separate listing organized to reveal all patents applicable to an active pharmaceutical ingredient;

To achieve value-for-money, Uganda should strengthen the patentability criteria for pharmaceutical products and especially for secondary patents. Argentina happens to have some of the best guidelines on this in the world. Thus, Section 4(1)(f) should read:

(f) to adopt regulations further specifying the application of patent standards to chemical entities and pharmaceutical and biologic medicines in accordance with Appendix A to this Act and any evidence-based adjustments thereof;

What is in the Bill as S.4 (1)(d) should read S.4 (1) (g), with an added statement to balance rights of right holders and those of users [consumers]. It should read:

(g) to promote inventiveness and innovativeness in Uganda and the achievement of a balance between the rights and interests of industrial property owners, users, and social and economic welfare; and

5. Register of Industrial Property

IN order to be useful, patent registers are going to have to be made available electronically, for the databases to be easily made accessible to applicants and for opposition proceedings. The section should thus be revised to read as follows:

- (1) The registrar shall maintain two registers one of which shall contain all industrial property applications received, and the other shall contain all industrial property and other rights granted under this Act, in which shall be recorded and numbered in the order of grant, and in respect of each patent, where appropriate, its lapse for non-payment of annual fees and all transactions to be recorded by virtue of this Act. In addition, the Register should maintain accessible databases for information on pharmaceutical and biologic medicines patents as specified in Clause 4(1)(d) and of all foreign actions on identical subject matter patents as specified in Clause 4(1)(e).***

PART III—PATENTABILITY

IT is undesirable to have yet another definition of invention which is fully defined and clarified with respect to patents in subsequent sections. This section should be amended as such to focus only on the right to product and process inventions and some exclusions from patentability. The exclusions with respect to natural substances, plants and animals, and computers programs/code were expanded. TRIPS permits exclusions and as an example, we should borrow the language of the section from the Zanzibar legislation. The title and content for S.8 should hence be amended to read as follows:

8. Product and process of “inventions” and exclusions from patentability.

- (1) Subject to subsection (2), an invention may be, or may relate to, a product or a process.**
- (2) 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) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;**
 - (d) natural substances, even if purified, synthesized or otherwise isolated from nature; this provision shall not apply to the processes of isolating those natural substances from their original environment;**
 - (e) mere presentation of information;**
 - (f) the human body and all its elements in whole or in part;**

Uganda being an LDC could join other LDCs to seek a substantial extension of the 2016 waiver. Hence , an addition to the existing wording of S.8 (2) (j) should be made to ensure that the Act makes reference to the possibility of extension. It should read:

(j) pharmaceutical products, including micro-biological products and including processes for producing pharmaceutical products, until 1st January 2016, or thereafter as provided by a waiver or extension of pharmaceutical patent and data protections under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) at the World Trade Organization Council for TRIPS granted to Uganda individually or to least developed countries as a group so long as Uganda is so classified.

10. Novelty.

UNDER part (1) to this section, an additional statement should be added because it is desirable to apply global standard expertise with respect to prior art and to acknowledge that it is relevant to consider combination of prior art. The language of the section is borrowed from the Zanzibar law as a best practice. It should read:

(1) An invention is new if it is not anticipated by prior art or where a theoretical person who is highly skilled in the relevant area(s) could not derive the invention from a combination of prior disclosed art.

Further, to part (2) of this section, it is important to consider disclosure in multiple sources and inferred disclosures, not just single and explicit disclosures. The additional language is also from the Zanzibar law as a best practice. The subsection should read:

- (2) For the purposes of this Act, prior art consists of everything made available to the public anywhere in the world by means of written disclosure including drawings, published patent applications, and other illustrations or by oral disclosure, use, exhibition or other non-written means which shall also be considered prior art, including information implied in any disclosure or derived from a combination of prior disclosures, where the disclosure or disclosures occurred before the date of filing of the application or, if priority is claimed, before the priority date validly claimed in respect of the application.**

11. Inventive step

UNDER part 1 of this section, additions should be made to the subsection because the Act should not limit the standard of inventiveness directly or by implication to Uganda experts only. S.11 (1) was thus amended to read:

- (1) An invention shall be considered as involving an inventive step if, having regard to the prior art or combination of prior art relevant to the application claiming the inventions, as described in section 10(2), it would not have been obvious to a person or group of persons highly skilled in the relevant art(s) anywhere in the world and to which the invention relates on the date of the filing of the application or, if priority is claimed on the date validly claimed in respect of the invention.**

Under part 2, additional language from the India Patents Act sec. 3(d) is needed to minimize tendencies to evergreen or to extend patent monopolies on medicines. Also reference is made to Appendix A which is based on clear, best practice standards for second patents on chemical entities and pharmaceutical products in Argentina. There is hence an amendment of the subsection to read as follows:

- (2) At such time as product patents on pharmaceutical and micro-biological medicines may become available, the following shall not be considered to involve an inventive step:***
- (a) new forms, including polymorphs, pseudopolymorphs (hydrates and solvates), salts, esters or other derivatives, active metabolites, and pro-drugs of;***
 - (b) new uses and new methods of use of;***
 - (c) new combinations or admixtures of; and***
 - (d) new formulations and changes dosages of existing chemical entities or existing pharmaceutical products or micro-biological medicines unless they show significantly increased efficacy in the treatment or prevention of human illness or disease. Patents on such product shall be assessed by the registrar or his designee pursuant to the guidance in Appendix A.***

To this section a further part (3) is added, based on the anti-evergreening standard in India reprocess patents on pharmaceuticals. It reads:

- (3) At such time as process patents on pharmaceutical and micro-biological medicines may become available, changes to existing processes shall not be considered inventive unless the process entails at least one new reagent.***

16. Patents relating to micro-biological processes or products.

AN additional subsection (7) was added to this section because members agreed that it is useful to reference the explicit WTO TRIPS pharmaceutical waiver and any extension thereof. The subsection added reads:

(7) Pursuant to section 8(2)(j) patents on such micro-biological processes or products may not be granted until 1st January 2016 or any further extension of the pharmaceutical waiver by the WTO TRIPS Council for Uganda or Least Developed Countries.

PART V—APPLICATION, GRANT AND REFUSAL OF GRANT OF PATENT

21. Application for a patent.

UNDER S.21 (5) (a), it is desirable to have disclosures most likely to result in further carrying out of the invention. The subsection is re-written to read:

(5) The description shall—

(a) disclose the invention and all practicable modes, including specification of the best mode, of carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application, in full, clear, concise and exact terms as to enable a person who has ordinary skills in the art to make use of and to evaluate the claimed invention;

For S.21 (6), standard of disclosure skill should be limited to that of an ordinary skill in the art as opposed to “skill in the art”. The provision now reads:

(6) Disclosure of the claimed invention shall be considered sufficiently clear and complete if it provides information which is sufficient to allow that invention to be made and used by a person who has ordinary skill in the art on the filing date, without undue experimentation.

S.21 (17) should be added because it is desirable for the patent applicant to identify all patents on medicines with a readily identifiable and universally recognized reference. It is also relevant as a requirement to make reference to S.4 (1)(d) in as regards to the INI. The added text hence reads:

(17) In the event of an application for a patent whose subject matter relates in any way to a pharmaceutical or micro-biological product, or active ingredient, inert ingredient, formulation, dosage or usage thereof, or of any process patent relating to the manufacturer or synthesis of the above, the application shall include in the first sentence of the abstract a reference to the international non-proprietary name(s) (INN) of the product. If the INN is not assigned until after the patent application is filed, the applicants or current assignee of the patent shall file a supplemental notification to the Registrar referencing the patent application or granted patent and the INN thereof.

28. Filing Date and Examination of Application as to Form.

UNDER S.28 (2), participants were of the view that we make the number of times one can correct an application clear in the law. The provision was thus re-inforced to read as follows:

- (2) Where the registrar finds that the application does not, at the time of receipt, fulfill the requirements referred to in subsection (1), he or she shall invite the applicant to file the required correction and shall accord as the filing date the date of receipt of the required correction, but if no correction is made, the application shall be treated as if it had not been filed; the applicant shall be given only one opportunity to make the requested correction in the application.***

In as regards to the amount of time with in which an interested party can bring on opposition proceedings, members were of the view that we stick to 90 days to avoid long and tenous processes. S.28 (7) was thus revised to read as:

- (7) Within ninety days after the publication of the notice mentioned in section 29, any interested party, which shall be broadly construed and not limited to potential commercial competitors, may file with the registrar a notice of opposition.***

In relation to S.28, subsection 13 is deleted and 14 is revised because their current text requires LDCs to maintain a patent mailbox in accordance with Article 70 of the WTO TRIPS Agreement, yet the pharmaceutical waiver for LDCs can be reasonably read to exclude the need for the mailbox. This can also be read with a cross reference to S.7 (2). The provision is hence revised to read:

- (13) The remaining subsections of this section as well as section 32 shall apply to the inventions mentioned in section 8(2) (j) only after January 1, 2016 or any further waiver or extension thereof by the World Trade Organization.***

31. Examination as to Substance.

SUBSECTION (1) should be deleted because of the need for a new section to affirmatively ensure that there is a good examination of pharmaceutical product patents. The deleted provision is carried to the bottom of the sentence. The section should read:

- (1) The registrar may, by notice in the Gazette—
 - (a) direct that an application for a patent which relates to a specified field or specified technical fields shall be subject to an examination as to substance; or*
 - (b) amend any direction issued under paragraph (a).**
- (2) Where an application for a patent satisfies the requirements specified in section 28(1) and the subject matter of the application does not fall within a technical field specified under subsection (1) or (11), the registrar shall notify the applicant and the applicant shall, within three years from the filing date of the application, submit a request in the prescribed form for the examination of the application under subsection (4).*
- (3) Where no request is made under subsection (2) within the prescribed period, the application shall be taken to be abandoned.*
- (4) Where a request is filed under subsection (2), the registrar shall cause an examination of the application to be made as to whether—
 - (a) the invention in respect of which the application is made is patentable within the meaning of this Act; and*
 - (b) the application complies with all requirements of this Act.**

In relation to S.31 (9), it is extremely important that the public have access to information on patent decisions. Thus this provision is revised with this emphasis included as follows:

(9) Where, in spite of any observation or amendment submitted by the applicant, the registrar finds that any of the conditions referred to in this Act are not fulfilled; the registrar shall refuse to grant a patent and notify the applicant accordingly. The registrar shall keep a registry or publicly available listing of withdrawn, denied, or suspended patent applications.

Finally what was S.31 (1) is carried to the end to read S.31 (11), because of the importance of medicines, patent applications on them should be closely scrutinized once they are allowed. It should read:

(11) An examination shall be required with respect to chemical entities and pharmaceutical and micro-biological products concerning the criteria described in section 11(2) and the guidance in Appendix A, if and when such applications are allowed.

32. Grant, Registration, and Publication and Post-Grant Opposition of a Patent

THE Bill does not provide for post grant provisions, yet it is necessary to have these included in case the registry made a mistake in granting one. The title of the section is thus revised to read as is above.

Stakeholders recommended during a consultative meeting held in March 2012 that an administrative post-grant opposition procedure be adopted in line with the EAC Guidelines. Post-grant oppositions have been used successfully in India. They are less costly and in-expensive. In addition, the Registry is not exposed to any liability because of post-grant opposition procedures. Additional sub-clauses to the section are proposed as below:

- (5) In the event a patent is granted, any interested party may petition the registrar to reconsider the grant on the grounds that the patent fails any requirement of this Act. Such petition must be filed within one calendar year of the published granted of the patent and shall specify the grounds thereof. An applicant can file only one post-grant opposition.***
- (6) The notice of reconsideration shall identify the opposed granted patent, as well as the grounds that the opponent considers relevant to bar the grant as well as all relevant evidence.***
- (7) The failure to meet the formal or substantive conditions of patentability in sections 9, 10, 11, 12, 13, 21 and 25 or in any Guidance from the Registrar may be alleged by the post-grant opponent.***

- (10) The registrar shall give notice of the post-grant opposition in the Gazette.***
- (11) The patent holder may within sixty days from the publication of the notice of opposition file a counter-statement.***
- (12) The registrar may, if he or she considers fit, grant a hearing pursuant to Regulation, at which the patent holder and the post-grant opponent may argue and counter-argue their case and submit additional evidence, if available, including oral evidence.***
- (13) The registrar may reverse or revoke the grant of the patent if satisfied that it fails to meet formal or substantive conditions of patentability.***

PART VI— INTERNATIONAL APPLICATIONS

35. Unsearched or Unexamined International Applications.

S.35 (4), is revisited to include the criteria for patentability and emphasis on the fact that there can only be one chance to amend an application. The provision should read:

- (2) The registrar may refuse to grant a patent if it is apparent from an international search report or an international preliminary examination report that the invention which is claimed in an international application does not fulfill the requirements of novelty, inventive step, industrial applicability, or required disclosures unless the applicant either satisfies the registrar that the requirements have been fulfilled or amends the claims in such a way that fulfils the requirements. The applicant shall have only one opportunity to amend the claims.*

PART VII— RIGHTS AND OBLIGATIONS OF THE APPLICANT OR THE OWNER OF THE INVENTION

38. Rights of the Owner.

PART (c) to S.38 (1) should be deleted because the Act is going to exclude patents on new uses.

And to part (2) of the section is added exceptional statement to make sure there is an exclusion for compulsory licensing. The sub-clause should read:

(2) After the grant of the patent, and within the terms of this section, the owner of the patent has the right to preclude any person from exploiting the patented invention in the manner referred to in subsection (1), except to the extent that the other person has obtained a compulsory or government use license or been permitted to continue such use by a order of a court of competent jurisdiction.

39. Obligations of the Owner.

THE language of this section is revised to provide for only the best mode and clarity is also made in as regards to obligations of the Owner. It should read:

The applicant or the owner of an invention shall have the following obligations—

- (a) to disclose the invention in a clear and complete manner, and in particular to indicate **the best mode** for carrying out the invention, in accordance with the requirements, and subject to the sanctions, applicable under this Act;*
- (b) to give information concerning corresponding foreign applications, **including and grants, denials, revocations, invalidations, suspensions or lapses;***

40. Remedies.

THERE is need to have remedies set out in one place. It is confusing to have them set out in two different places. Subsections 16 and 17 of section 102 have been placed in section 40 in substitution of the differently drafted provisions (subsection (1)(c) and subsection 2 already there because they are clearer and more inclusive. The entire section should read:

- (1) *The owner of a patent has the right—***
 - (a) *to seek an injunction to restrain the performance or the likely performance, by any person without his or her authorization, of any of the acts referred to in section 38;***
 - (b) *to claim damages from any person who, having knowledge of the patent, performs any of the acts referred to in section 38, without the owner's authorization;***

- (2) *The court may order the infringer to pay damages relating to acts of infringement of patent rights practised—***
 - (a) *after the date on which the patent application was published, in accordance with section 29; or***
 - (b) *after the date on which the patent applicant gave notice to the alleged infringer of the contents of the application; or***
 - (c) *after the date on which the alleged infringer acquired knowledge of the contents of the application by any means.***

- (3) *The request for the court to order the payment of damages under subsection (1) may be filed only after the patent in question is granted.***

43. Limitation of Rights.

S.43 (1) should be deleted for being inconsistent with section 44(a) which is broader. Hence S.43 (2) becomes S.43 (1). This sub-clause be made broader as with Kenya to allow parallel importation of medicines produced pursuant to a compulsory license. Hence it should read:

(1) The rights under the patent do not extend to acts in respect of articles which have been put on the market in Uganda or in any other country or imported into Uganda by the owner of the patent or with his or by any party authorized to use the invention, consequently exhausting the patent owner's rights and thereby permitting the importation and sale of such products into Uganda.

S.43 (4) & (5) should be deleted for being redundant to section 41 on prior use. Further, S.43 (7) & (8) should be deleted because compulsory licenses and government use licenses are covered extensively elsewhere and are separate from S. 30 limited exceptions under TRIPS Art. 31. In addition, Subsection 8 is inconsistent with the proposals on exclusions from patentability.

44. Additional limited exception to exclusive rights.

As there are already proposals to provide for exceptions in prior clauses, this clause is important because it could be broadened to refer to research and educational purposes. Part (1) (a) & (b) was thus revised to read:

It is not an infringement of a patent to use the patented invention without the authorization of the patent holder in any of the following circumstances—

- (a) to carry out any acts related to experimental use or research on or relating to the patented invention, whether for scientific or commercial purposes;***
- (b) to make use of a patented invention for teaching or educational purposes***

45. ARIPO Protocol on patents.

The provisions for this section should be revised to refer to the “Harare Protocol on Patents and Industrial Designs” as that is the rightful name of the protocol it refers to. Also an additional clause is proposed because Uganda does not have to patent pharmaceuticals at present because of the WTO waiver, all pharmaceutical patents from ARIPO should be promptly rejected by the registrar. Hence it should read:

- (1) A patent, in respect of which Uganda is a designated state, granted by ARIPO by virtue of the Harare Protocol has the same effect in Uganda as a patent granted under this Act except where the registrar communicates to ARIPO, in respect of the application of the patent, a decision in accordance with the provisions of the Protocol that if a patent is granted by ARIPO, that patent shall have no effect in Uganda.***

- (2) The registrar shall promptly reject all pharmaceutical and medicines-related micro-biological patents until the 1 January 2016 WTO pharmaceutical waiver or as further extend by the WTO.***

PART X— CONTRACTUAL LICENCES

55. Prohibited terms in a licence contract.

UNDER S.55 (2), (u), because Patent holders almost always put territorial limits on their licenses especially for rich country markets. Ugandan companies may never get any licenses if this clause is left as is. We thus revise it to read as follows:

(2) Without prejudice to subsection (1) the following terms in a licence contract shall be taken to have the effect described in that subsection to—

(u) impose restrictions which prevent or hinder export by means of territorial or quantitative limitations or prior approval for export or export prices of products or increased rates of payments for exportable products resulting from the technology licensed, except to territories where the patent holder has a valid patent;

In S.55 (2) (v), it is highly desirable to have quality control standards, especially for medicines. The sub-clause is thus revised to read as follows:

(v) impose quality control methods or standards not needed by the licensee, except to meet the requirement of a guarantee or when the product bears a trade mark, or trade name of the licensor, except that Good Manufacturing Practice and other relevant quality controls can be established with respect to pharmaceutical products;

Finally in S.55 (2) (z), if there is a patent where you want to export, then you should pay royalties for it. Additional clauses to (z) are made as well to minimize abusive practices by licensors that should be avoided. It now reads as follows:

- (z) require payment of royalty for patents granted outside Uganda, except to the extent the licensee exports to a territory where the patent is protected;***
- (aa) apply different conditions to similar transactions with other trading parties, and that placing the licensee at a competitive disadvantage; and***
- (ab) make the licence contract subject to acceptance of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of the contracts;***
- (ac) require exclusive grant-back licenses with respect to inventions and other innovations to the licensor;***
- (ad) fail to pay reasonable compensation or royalties for any non-exclusive grant-back license or rights;***
- (ae) require the licensee to not oppose or seek revocation or invalidation of the grant of a patent;***
- (af) require the licensee not to become a compulsory licensee with respect to a compulsory license issued in Uganda or elsewhere.***

58. Compulsory licences for non-working and similar other reasons.

DURING the consultation, stakeholders were of the view that because court proceedings are protracted and expensive both to litigants and to the judiciary, it is highly preferable to have administrative procedures for the grant of a compulsory license. Although the application is to the Minister, he or she should consult with relevant Ministries, Departments, and Agency as referenced further in this section. Additions to the section are suggested to read as follows:

- (1) After the expiration of four years from the filing date of an application or three years from the grant of a patent, whichever last expires, a person may apply to the *Minister* for a licence to exploit the patented invention on the grounds that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Uganda.**
- (2) Notwithstanding subsection (1), a non-voluntary licence shall not be granted if the owner of the patent satisfies *the court Minister in consultation with relevant Ministries, Departments, and Agencies* that circumstances exist which justify the fact that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Uganda.**
- (3) In addition to compulsory licenses granted under subsection (1), a compulsory license can be issued on any other public interest or public health grounds, including but not limited to:**

 - (a) national security, national emergency or matter of extreme urgency, nutrition, health, or the development of other vital sectors of the economy; or**
 - (b) a judicial or administrative body has determined that the manner of exploitation, by the patent owner or his licensee, is anticompetitive and the Minister in consultation with relevant Ministries, Departments, and Agencies is satisfied that a compulsory license in accordance with this subsection would remedy such practice in which case there is no limit on the quantity of product that may be exported; or**
 - (c) the prices are not affordable or are excessive for the ordinary Ugandan or the invention is not available in sufficient quantities or qualities either through manufacture in Uganda or through importation; or,**
 - (d) the desirability of multiple and uninterrupted sources of supplies of essential commodities, including medicines; or**
 - (e) the desirability of combining patented technologies,**

particularly rational, fixed-dose medicines, for the benefit of users; or

(f) the applicant for the license has unsuccessfully endeavoured during a period of 90 calendar days to obtain the patent holder's consent for the voluntary use of the patented invention under reasonable terms and conditions; or

Also an example drawn from the Zanzibar law, it is important to have open-ended and specific grounds for issuing compulsory licenses. As such, (3)(g) to this section is crafted to read as follows:

(g) the promotion of technology transfer and industrial development.

In line with the recommendations of the March 2012 consultative meeting, it is desirable to specify that there can be both domestic and foreign licensees as allowed by TRIPS. So part (4) to this section reflects this and should read thus:

(4) Compulsory licenses may be granted to domestic or foreign entities and may be granted to one or more licensees, including an open license to all that can satisfy the conditions of the license.

It should be noted that the TRIPS agreement requires that compulsory licenses be primarily for domestic use, but that the 30 August 2003 Mechanism does allow export to members of a regional trade group comprised of more than 50% LDCs. An additional clause is proposed to reflect this:

(5) Compulsory licenses on pharmaceutical products, if and when such patents are granted in Uganda, shall be issued when requested pursuant to the Decision of the General Council of the World Trade Organization of August 30, 2003 (30 August 2003 Mechanism) or pursuant to proposed Article 31bis of the TRIPS Agreement or any other provision, which is to replace

the 30 August 2003 Mechanism, if and when adopted, so long as required notifications and licenses are obtained. Uganda may use the 30 August 2003 Mechanism either as an exporter or as an importer, but as an importer only so long as it is a Least Developed Country or otherwise certifies that it has insufficient manufacturing capacity for the relevant pharmaceutical product. In the event that a Uganda compulsory licensee exports under this provision, it is not bound by the requirement section 61(b) that a compulsory license must be predominantly for domestic or regional use.

Finally under this section, TRIPS permits establishment of remuneration guidelines and the 4% has been recommended by UNDP and others in the past. Hence, a clause to incorporate that good practice standard added as follows:

(7) The remuneration of a compulsory license shall be determined as a percentage of net sales, taking into account the value of the license on relevant market or markets to be served by the license, but shall not exceed 4%; the remuneration shall be reduced or excluded when the license is granted to remedy practices found to be anti-competitive.

59. Compulsory licences based upon interdependence of patents and for research tool patents.

THERE is need to provide for research tool patents as recommended by the TEAC *Guidelines on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation*. The title of the section is thus revised to include this as well as an additional clause to the section reading to this effect as follows:

(5) Where a patent is granted on a research tool, there shall be a license as of right to use the research tool upon payment of adequate remuneration to the patent holders by the user as hereinafter described.

60. Preconditions for grant of compulsory licences.

It is important to specify a time frame as otherwise negotiations can be dragged out by right holders. So S.60 (1)(a) is reviewed to read as follows:

- (1) *A compulsory licence shall not be granted unless the person requesting the licence—*
- (a) *satisfies the Minister in consultation with relevant Ministries, Departments, and Agencies that he or she has requested the owner of the patent for a contract licence but has been unable to obtain the licence contract on reasonable commercial terms and within a reasonable time, which period of time shall not be longer than 90 calendar days; and*

It is also important that qualification standards are appropriate in certain contexts and these should be made a part of S.60 (1) (b) as follows:

- (c) *offers a guarantee satisfactory to the court to work the relevant invention sufficiently to remedy the deficiencies or to satisfy the requirements which gave rise to his or her request and that he or she is otherwise qualified to work the patent.*

In line with this section, another lawful discussion of not requiring prior negotiations is discussed in Part XI, but it does not hurt to mention it is as well:

- (2) *The requirement under subsection (1) (a) with respect to prior negotiations shall be waived in the case of a national emergency or other circumstances of extreme urgency, of public, non-commercial use pursuant to Part XI or where the application is based on anti-competitive practices; except that the registrar shall notify the owner of the patent as soon as reasonably possible of the waiver.*

61. Grant and terms of compulsory licences.

IN order to increase administrative efficiency, licenses need not be limited to just one licensee and in some instances it is important to promote broad competition. S.61 (1)(a) should be reviewed to read as follows:

When considering a request for a compulsory licence, the Minister in consultation with relevant Ministries, Departments, and Agencies shall decide whether a compulsory licence may be granted to one or more licensees, including an open license for all persons and entities that can satisfy the terms of the license, and shall, if it decides in favour of the grant and after taking into account any terms agreed by the parties, proceed to fix the terms which shall be taken to constitute a valid contract between the parties and shall be governed by the provisions on contractual licences.

Under part (2) (b) of this section, there should be no general exception to the predominantly domestic use rule, except with respect to export to regional LDC groups. But Uganda can try to include it directly with reference to 30 August 2003 Mechanism. The sub section should thus be reviewed to read as follows:

- (2) When fixing the terms under subsection (1), the court shall ensure that the compulsory licence—***
- (b) is limited predominantly for the supply of the domestic or a regional market to which Uganda belongs that is comprised of more than 50% Least Developed Countries, to the extent so allowed by the 30 August 2003 Mechanism;***

Emphasis is proposed for (2) (c) &(e) by adding provision for “Licensees” and “adequate remuneration” thereof respectively. The provisions should read as follows:

- (c) does not entitle the licensee or *licensees* to grant further licences without the consent of the owner of the patent;**
- (d) is non-exclusive;**
- (e) provides for the payment to the owner of the patent of *adequate* remuneration which is equitable having regard to all the circumstances of the case, including the economic and social value of the licence *in the relevant domestic market*;**

Further, it is important to provide for remuneration guidelines as under TRIPS Agreement. An additional clause is thus added to reflect this as:

- (f) *The remuneration of a compulsory license shall be determined as a percentage of net sales, taking into account the value of the license on relevant market or markets to be served by the license, but shall not exceed 4%; the remuneration shall be reduced or excluded when the license is granted to remedy practices found to be anti-competitive;***

Also as an addition, according to UNDP remuneration guidelines, it is important to have a provision on apportionment. Hence, an additional provision is proposed to read as follows:

- (g) *Where two or more patents are incorporated into an integrated product, the royalty determined above shall be apportioned according to the respective contribution of each patent to the value of the product.***

Also a provision as is specifically provided for in the 30 August 2003 Mechanism is added as follows:

(h) Where importation takes place pursuant to the 30 August 2003 Mechanism or TRIPS Article 31bis, if adopted, and the exporting country issues a compulsory license for the same patented invention, payment of further remuneration on any Ugandan compulsory license is waived.

Clarity for administrative procedures is also provided for in part (3) of the section and is reviewed as follows:

(3) Government agencies and the patent owner shall have the right to appear and be heard at the hearing before the Minister or his or her designee on an application for a compulsory licence.

Finally, it should be noted under this section that It is useful to have an administrative appeal mechanism rather than judicial review. A provision to this effect is suggested to read as follows:

(4) A patent-holder aggrieved by a compulsory license under this section may appeal to a higher administrative body but such appeal shall not stay or suspend the license.

62. Transfer of compulsory licence.

THIS section should be reviewed to reflect administrative procedures to be followed. It should read:

A compulsory licence may be transferred only with that part of the industrial undertaking or its goodwill, in which the relevant invention is used and the transfer shall not be valid until the consent of the Minister in consultation with relevant Ministries, Departments, and Agencies is obtained.

63. Cancellation of compulsory licence.

THIS section should be reviewed to reflect administrative procedures to be followed. It should read:

- (1) On the application of an interested party, the Minister in consultation with relevant Ministries, Departments, and Agencies may cancel a compulsory licence if—***

In part (2), this section should consider regulatory approval/registration for medicines which often takes three years. This part of the section should read:

- (2) On the application of the owner of the patent or on his own motion, the Minister in consultation with relevant Ministries, Departments, and Agencies may cancel the compulsory licence if, within three years from the grant of the licence, the licensee has not taken the necessary steps to work the relevant invention sufficiently so as to remedy the deficiencies or to satisfy the requirements which gave rise to his or her application for the licence.***

It is important to take into account legitimate interests of right holders in the law, but also clarity should be made in as to administrative procedures that should be consulted as below:

- (3) On the application of the owner of the patent or the licensee, the Minister in consultation with relevant Ministries, Departments, and Agencies may vary the terms of a compulsory licence if new facts on the owner's part justify the variation and in particular if the patent owner has granted a contractual licence on more favourable terms, so long as the legitimate interests of the licensee are protected.***

Under this section, it is important to allow discretion by decision makers in granting Compulsory Licensing. A provision on this is proposed to read as follows:

- (4) *Notwithstanding an application to cancel a compulsory license, the relevant decision-maker may decide not to terminate if satisfied that there is a need to protect the legitimate interests of the licensee in light of preparations and investments made.***

64. Registration of grant, cancellation or variation

THE administrative procedures that should apply to the case are clarified. The provision should read:

Where the Minister in consultation with relevant Ministries, Departments, and Agencies grants, cancels or varies the term of a compulsory licence, the Minister shall instruct the registrar to record the grant, cancellation or variation in the register without payment of any fee.

PART XI— EXPLOITATION OF PATENTED INVENTIONS BY THE GOVERNMENT OR BY THIRD PARTIES AUTHORISED BY THE GOVERNMENT

66. Exploitation of patented inventions by the Government or by third parties authorised by the Government (Government use).

THE provision for national emergency should be deleted as these are already provided for later in S.66 (4). The provision is hence reviewed to be in line with Article 31 of the TRIPS Agreement:

(1) Subject to this section, where—

(a) the public interest, in particular, national security, nutrition, health, environmental conservation, or the development of other vital sectors of the national economy requires; or

(a) any Government Agency determines that the manner of exploitation of an invention by the owner of the patent or his or her licensee is not competitive,

the Minister shall for the purpose of public, non-commercial use make, use, exercise, import, keep and vend any patented invention upon application to him or her in the prescribed form and after consultation with the relevant ministry. The government is not required to enter into prior negotiations with the patent-holder for public, non-commercial use. Where Minister or relevant ministry, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

It is also notable that the order may be revoked by the Minister after consultation with the relevant ministry. An additional statement is thus suggested to mention this in the law:

(2) An order under subsection (1) shall remain in force until it is revoked by the minister in writing, after consultation with the relevant ministries, after giving six months prior notice of his or her intention to revoke to the licensed party named or described in the order.

TRIPS does not require the payment of adequate remuneration for a government use license. The sub section should therefore read as follows:

(2) An order made under subsection (2) shall not require the payment of compensation to the government use licence holder or any other party interested.

Part (4) of S. 66 should be deleted for being redundant as it is necessary to give notice of a process patent.

Part (5) & (6) should also be deleted for being redundant and not necessary as process patents are covered by the reference to any patented invention in subsection 1, prior negotiations for government use licenses is also not required by TRIPS as was initially provided for in (6).

Section 66 should be rearranged as a whole, and the new S.66 (6) reviewed to adopt the language of the UNDP remuneration guidelines. It should read as follows:

(6) The remuneration of a government use license shall be determined as a percentage of net sales or in the case of government production cost of production, but shall not exceed 4%;

S.66 (11) should be revised to reflect the fact that Government use is probably necessarily domestic and probably public sector. The August 30 Mechanism allows further export within the region. So it is right to keep this in. it should read:

(11) The exploitation of the invention under an order made under this section shall be primarily for the supply of the domestic or regional market to the extent permitted by the 30 August 2003 Mechanism.

Under S.66 (13), emphasis laid on appeals against government use orders may not stay or suspend the same. The provision should state:

(13) A person who is aggrieved by a Government use under this section may appeal to the court, but any such appeal shall not stay or suspend the Government use.

PART XII— UTILITY MODELS

68. Applicability of provisions relating to patents.

UNDER this section, reference is made to Section 40 which covers patent remedies while there is a separate remedies section for utility models and industrial designs under section 93. It should read:

- (1) Subject to this section, Parts III, IV, V, VII, VIII, IX, X, XI, XV and XVI, except section 40, shall apply, with the necessary modifications, to utility model certificates or applications for them, as the case may be.*

69. Special provisions relating to utility model certificates.

UNDER this section an additional provision is suggested to emphasize that it is even more undesirable to have pharmaceutical utility models than pharmaceutical patents which are currently excluded under the WTO waiver. The additional provision should read:

- (3) A utility model certificate shall not be available for pharmaceutical products or processes, including those relating to micro-biological medicines.*

PART XIII— INDUSTRIAL DESIGNS

71. Definition of an industrial design.

AN additional clause is needed in this section to ensure generics, which ordinarily have a close appearance to the originator product, should never bear the trademark. It should read:

- (3) The protection of industrial designs and trade dress shall not apply to pharmaceutical products, where product differentiation of generic equivalents is likely to cause confusion or inconvenience to patients or where differentiation might adversely affect bio-equivalence. In no instance shall this exception permit the willful violation of registered trademark rights.*

PART XV— SURRENDER, REVOCATION AND INVALIDATION

90. Revocation or invalidation.

INVALIDATION or revocation should be available at any time as an invalid patent should not be allowed to be enforced under any circumstances. S.90 (2) is hence reviewed to read as follows:

- (2) An interested person may, within the term of a patent, utility model or an industrial design, request the court to revoke or invalidate the patent, utility model or industrial design registration.***

Under part (3)(d), (e), & (f) of this section, reference to the standards of patentability should be made as amended to do so. These sections should read as follows:

- (3) The court shall revoke or invalidate the registration of the patent or the utility model or industrial design on any of the following grounds that—***
- (d) the invention involves no inventive step in terms of **section 11**;***
 - (e) the invention is not novel or new in terms of **section 10**;***
 - (f) the patent does not fully and adequately describe and ascertain the invention and the manner in which it is to be performed in terms of **sections 21, 25, and 39**;***

91. Effect of revocation or invalidation

An additional provision is proposed to prevent unjust enrichment for an industrial property right improvidently granted. The added part should read:

- (3) Where a patent, utility model, or industrial design is revoked or invalidated, the patent applicant shall be ordered to repay with interest any royalties or other compensation he received from voluntary, government use or compulsory licensees.***

PART XVI—INFRINGEMENT

93. Remedies for utility models and industrial designs.

INSTEAD of keeping the wording of the title to “relief”, it is better to stick to reference to “remedies” as that is the phraseology consistent with the Act in reference to any section with relation to relief. And, since proposals for remedies to patents have already been made, this section should only refer to Utility models and industrial designs.

Also under part (c) to this section, a provision for adequate remuneration for past and continued use of a utility model or industrial design should be added. The wording is crafted as follows:

Upon the request of the owner of the registered utility model or an industrial design, the court may grant, any of the following reliefs—

- (a) an injunction to prevent infringement where infringement is imminent or to prohibit the continuation of the infringement once infringement has started.***
- (b) damages; or***
- (c) any other remedy provided for in law, including the payment of adequate remuneration for the past and continued future use of the utility model or industrial design, especially, but not limited to, if it is in the public interest to do so.***

96. Criminal proceedings.

SECTION 96 should be deleted from the bill because it is undesirable to criminalize patent infringement since the validity of patent claims is so hard to determine and since there is a general interest in competition. The patent holder has many other infringement remedies. The EAC *Guidelines on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation* also do not recommend use of criminal proceedings in patent infringement claims. In addition, the March 2012 stakeholder consultative meeting noted:

- ***Whether or not there is patent infringement, only specialists will be able to determine that infringement. Such capacity is lacking in Uganda's criminal courts.***
- ***That a person may not even be aware that his/ her act is infringing a patent;***
- ***That getting accurate information about patent status is difficult and often impossible in LDCs***
- ***That a patent granted may still be found invalid or revoked when scrutinized by courts, due to lack of patentability requirements, insufficient disclosure, or other reasons;***
- ***That criminal sanctions could be abused by patent holders to intimidate competitors and force them out of market even if infringement did not exist;***
- ***That criminalizing patent infringement will hurt local SMEs since they will be deterred from attempting to "reverse engineer" or "invent around" an invention for fear that there could be a potential patent infringement.***
- ***That even in developed countries patent infringement is not dealt with criminal sanctions as a preferred method.***
- ***That patent rights are individual property rights that need not make use of the state's meager funds to enforce their rights.***

97. Presumption of use of patented process.

THE provisions under this section should be deleted and replaced with provisions of subsections (19)-(21) previously found in section 102 because they are superior to the deleted language. The content of the previous language is captured in the new subpart (2). It should read:

- (1) For the purposes of civil proceedings in respect of the infringement of rights of the patent owner, if the subject matter of a patent is a process for obtaining a product, the court may order the defendant to prove that the process used to obtain an identical product is different from the patented process.*
- (2) Any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process in the following circumstances—*
 - (a) if the product obtained by the patented process is new; or*
 - (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.*
- (3) In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account by the court, which, among other measures, shall not facilitate those secrets to the plaintiff.*

99. Suspension of release by customs authorities

THIS section be deleted from the Bill entirely as it is highly undesirable. Pirating does not accurately apply to patented goods. Border agents are unqualified to determine on their face whether a particular product violates a patent (unlike criminal trademark and copyright violations which are obvious on their face.)

PART XVII— SPECIAL PROVISIONS ON ENFORCEMENT OF PATENT RIGHTS BY LICENSEES

102. Special provisions on enforcement of patent rights by licensees.

UNDER this section, except with respect to remedies for licensees, former subsection 2, virtually all of this section should be deleted for being either duplicative of Section 40 or inconsistent with it. However, subsections 16 and 17 should be moved into section 40 and subsections 19-21 moved into section 93 because they have valuable alternative content in each section, respectively. What is left should read:

On the request of an exclusive licensee, or of a compulsory or government use licensee, or of a non-exclusive licensee if he or she has requested the owner of the patent to institute court proceedings for a specific relief and the owner has refused or failed to do so within ninety days, the court may grant an injunction to prevent infringement or an imminent infringement and, where the infringer acted knowingly or with reasonable grounds to know, the court may award damages and grant any other remedy provided for in this Act.

PART XVIII—MISCELLANEOUS

110. Repeal of Cap. 216 and Cap. 218, transitional and savings provisions

UNDER this section, it should be noted that TRIPS allows non-enforcement of patents pursuant to the WTO LDC pharmaceutical waiver. As such there is need for an additional statement under S.110 (2) (a). It should read:

- (2) Where a patent was registered in Uganda under the former patent Act or where it was saved under that Act and the privileges and rights conferred by the registration were effective immediately before the commencement of this Act, then, subject to this section -*
- (a) the patent shall be treated in Uganda as if it had been granted under this Act, **except with respect to pharmaceutical products, including micro-biological materials and processes;***

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