UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

Development Dimensions of Intellectual Property in Uganda: Transfer of Technology, Access to Medicines and Textbooks



A Report by the UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development





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### **Overview**



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UNCTAD/PCB/2009/13 (Overview)

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#### Foreword

Intellectual property rights (IPRs) have never been more economically and politically important or controversial than they are today. Considerable increases in royalty payments and licensing fees in most areas of the world and the inclusion of intellectual property provisions in regional and bilateral trade and investment agreements over the past few years illustrate the fact that IPRs have become a major economic, trade and investment issue.

Responding to the new mandate received from member States at the Ministerial Conference in Accra, as well as to the requests contained in the World Intellectual Property Organization (WIPO) Development Agenda and the World Health Assembly's Resolution 61.21 on a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, the UNCTAD secretariat is implementing a work programme on the development dimensions of IPRs.

In our joint Project on Intellectual Property Rights and Sustainable Development, UNCTAD and the International Centre for Trade and Sustainable Development (ICTSD) seek to address the concerns voiced by developing countries with respect to the implementation of the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement, the WIPO Development Agenda and other new developments in the area of IPRs contained in multilateral treaties and regional and bilateral free trade agreements.<sup>1</sup>

A key component of the project is the preparation of countryspecific Development Dimensions of Intellectual Property (DDIP)

<sup>&</sup>lt;sup>1</sup> Activities under the project, including the preparation of the present report, have been funded by the United Kingdom's Department for International Development.

Reports, which seek to assist developing countries and least developed countries in integrating intellectual property issues into their specific development objectives.

The present *DDIP Report for Uganda* provides a number of policy recommendations on how to implement international intellectual property obligations coherently with other domestic public policies, such as the transfer and dissemination of technology and knowledge, as well as the promotion of access to medicines and textbooks in a pro-competitive environment. It is hoped that this report will provide some useful guidance to policymakers and intellectual property stakeholders in Uganda in the context of ongoing legislative reforms.

Parfoli

Supachai Panitchpakdi Secretary-General of UNCTAD

#### Acknowledgments

This *DDIP* Report for Uganda was prepared by Christoph Spennemann of UNCTAD's Intellectual Property Unit, Investment Capacity-Building Branch of the Division on Investment and Enterprise, under the supervision of Kiyoshi Adachi. James Zhan provided overall guidance. This report is based on a series of stakeholder interviews conducted in Kampala in May 2008, by a team led by Christoph Spennemann and including Sandy Harnisch and Achal Prabhala. In addition, this report has benefited from a peer review meeting with domestic stakeholders at Kampala in June 2009.

UNCTAD and ICTSD gratefully acknowledge the important assistance by Uganda's Ministry of Tourism, Trade and Industry (MTTI) in organizing the stakeholder interviews and the peer review, in particular as provided by Elizabeth Tamale, Principal Commercial Officer, MTTI; Georgina Nampeera, Commercial Officer, MTTI; and Emmanuel Atwiine, Commercial Officer, MTTI.

Extensive comments on earlier versions of this report were made by Joseph D. Rubalema, Director Product Development, Uganda Industrial Research Institute (UIRI); Apollo E. Muhairwe, Executive Secretary, Uganda National Drug Authority; Pedro Roffe, ICTSD; Ermias Tekeste Biadgleng, Legal Expert, UNCTAD; Malebona Precious Matsoso, Director, World Health Organization (WHO) Secretariat on Public Health, Innovation and Intellectual Property; Lembit Rägo, Coordinator for Quality Assurance and Safety: Medicines, Essential Medicines and Pharmaceutical Policies, WHO; and Deus K. Mubangizi, Technical Officer, WHO Prequalification Programme. The assistance of Carly Huth and Haruka Miki, interns, in the finalization of this document is gratefully acknowledged.

#### Background

The present *DDIP Report for Uganda* was prepared in response to a request submitted to UNCTAD in 2008 by Uganda's MTTI. Against the background of previous work carried out by ICTSD and SAANA Consulting, MTTI requested the UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development to examine whether the country's intellectual property policies are in line with the following development objectives:

- (a) Access to technology transfer;
- (b) Access to medicines (patent laws and test data protection);
- (c) Access to textbooks (copyrights).

In carrying out this work, UNCTAD put considerable emphasis on the need to tailor a country's intellectual property laws to its technological and economic stage of development. The preparation of this report has been guided by the desire to make recommendations that respond to the situation actually prevailing in the country. For this reason, DDIP work has not been limited to deskwork, but is based on a series of interviews and consultations conducted with domestic stakeholders in Kampala in May 2008, as arranged by MTTI. The final report takes account of comments received from domestic stakeholders in early 2009, as well as during a peer review meeting in Kampala on 25 and 26 June 2009, organized by MTTI.

The DDIP main report is organized in three chapters, featuring the interface of intellectual property with the issues of technology transfer, access to medicines and access to textbooks, respectively. Each chapter, after describing the factual background in Uganda and the pertinent institutional set-up, provides a detailed analysis of the domestic intellectual property legal framework, before making recommendations for suggested legislative amendments. The objective of these recommendations is to provide guidance on how to use the country's domestic intellectual property laws to promote the above-mentioned development objectives.

This overview was prepared to facilitate the reader's quick access to the recommendations made in the main report. In the overview, the recommendations are boxed, followed by references to provisions of laws that would need to be reviewed, when appropriate. Technical details, including footnote references, are reserved for the main report, which authorities and interested parties are invited to consult for all purposes. The *DDIP Report* and its overview will be made available at http://www.unctad.org/tot-ip and http://www.iprsonline.org.

#### Introduction

Despite Uganda being among the fastest growing economies in Africa, with sustained growth rates of an average 7.8 per cent since 2000, the country was ranked only 154<sup>th</sup> out of 177 countries on the United Nations Development Programme's Human Development Index in 2007/2008. Agriculture remains the dominant sector in Uganda's economy. Reliance on agricultural commodities, combined with infrastructural gaps, low human development, a low gross domestic product and a relatively low combined primary, secondary and tertiary gross education enrolment ratio of 63 per cent indicate that Uganda's scientific and technological development is currently at a low stage. Thus, an important public policy objective in Uganda is to improve, upgrade and strengthen its scientific and technological base. For this purpose, a sustained and targeted policy on access, dissemination and transfer of technology is urgently needed.

Notwithstanding recent successes in improved treatments, HIV/AIDS, malaria, tuberculosis and certain diseases still are threats to the population. Civil society organizations have emphasized the increasing demand for antiretrovirals in Uganda. which in their view far outstrip the capacity of the response system and available financing. About 80 per cent of the drugs procured by the government are imported. The costs for these imports have been rising sharply, from \$3 million in 2004/2005 to \$54 million in 2007/2008. With a view to minimizing drug costs, the National Drug Policy encourages the procurement of locally produced drugs. Next to rising prices for pharmaceuticals, the country's poor health care infrastructure, weak management of public (foreign donors') funds and a shortage of funds available for the National Drug Authority may be identified as the main reasons for the continued lack of access by large parts of the population to treatments for HIV/AIDS, malaria and tuberculosis. Thus, ensuring access to affordable medicines and adapting the

regulatory and legal framework to this objective is a major national priority.

Finally, the government, despite important education-related expenditures, has not been able to bridge the existing gap in students' access to textbooks, especially in secondary and tertiary education. Students, unable to afford copyrighted textbooks, respond through large-scale, unauthorized photocopying. The awareness of copyright implications is very low, not only among students and teaching staff, but also among copyright owners regarding their rights. This results in a widespread lack of copyright enforcement. Thus, access to educational material through a forward-looking copyright policy is an important public policy objective of Uganda.

#### I. Intellectual Property and Technology Transfer

Uganda is currently at a low stage of technological development ...

Uganda's 2007 Communication to the WTO Council for TRIPS of Priority Needs for Technical and Financial Cooperation stresses that:

At this stage of Uganda's path to development, it is necessary for the country to seek and receive support from the international community on the use and management [of] IPRs in combination with well-designed government support measures that address domestic development needs such as the promotion and establishment of a domestic creative and innovative industry and the development of its technological base.

[...] However, much more can be done to strengthen our embryonic scientific and research institutions and implement appropriate interventions to reinforce existing national polices, incentives and programmes aimed at both the public and the private sector. Much more can also be done to encourage better-targeted incentives for transfer of technology by developed countries.

Comparable observations were made in a 2007 report developed for ICTSD, which found that "Uganda has a weak domestic scientific and technological base, relying on acquisition of foreign-owned technology and know-how to support industrial development."

### ... but has no overall strategy on how to attract and disseminate foreign technologies.

Efforts to promote the transfer and dissemination of technology are limited to certain industrial sectors, but there is a lack of an

overall including linkages strategy. and coordination bv technology-relevant government agencies. The overall objective of a strategy on technology transfer would be to promote general, coherent principles and move away from uncoordinated and merely sectoral initiatives. Such a strategy would have to be complemented by sectoral policies to facilitate technology transfer, as they already exist, for example in the areas of and communication technologies information (ICTs) and biotechnology. These policies should take account of the particular needs of a specific sector, which cannot be addressed by an overall strategy.

**Recommendation 1: Adopt a transfer of technology strategy.** In essence, an overall transfer of technology strategy should aim at building capacities in incremental innovation, and design the intellectual property tools to implement this objective. Sectoral policies should determine specific indicators of success of technological learning and dissemination. Possible elements of an overall strategy and of sectoral policies are outlined in chapter I (section 2) of the main report.

#### Uganda's level of technology development needs to be reflected in the country's institutional intellectual property and technology structure ...

Technological capacities may be promoted through the transfer of technologies by foreign investors, but such a transfer cannot take place without existing absorptive capacity in the host country. Local workers, in order to benefit from foreign expertise, need a certain level of technological knowledge, otherwise there will be no actual collaboration in the form of joint ventures or licensing agreements. Next to a well-designed educational system, a country's domestic institutional and legislative intellectual property system should be tailored to its level of technological development, allowing access to the information required to build domestic skills.

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One way of building domestic technological capacities is by extracting technical information from patent applications, even though it should be acknowledged that in certain cases, it may prove difficult for local researchers to effectively understand the patent description and claims. This requires, however, an efficient linkage between a country's intellectual property administration and its scientific and technological research institutions, which for the time being is not happening in Uganda. The Ugandan Registration Services Bureau (URSB) mainly registers IPRs with a view to collecting revenue, rather than with the objective of promoting technology development. According to interviewed stakeholders, there appears to be no interaction between URSB on the one hand and research institutes like the Uganda National Council for Science and Technology (UNCST). the Uganda Industrial Research Institute (UIRI) and the National Agricultural Research Organization.

### Recommendation 2: Institutional set-up of the intellectual property office.

(a) In order to better link domestic research institutions with the country's intellectual property administration, the government should consider the establishment of a national intellectual property office staffed with, inter alia, technical experts capable of extracting technical information from patent applications, in addition to legal and administrative staff for the intellectual property registration procedures;

(b) While the location of such an intellectual property office (within URSB, UNCST or elsewhere) is a matter of government choice, it seems essential to ensure that such an office benefits from the technical expertise available in institutions such as UNCST, UIRI, the National Agricultural Research Organization and others. The Kenya Intellectual Property Institute or the Ethiopian Intellectual Property Office may serve as examples in this regard. In order to ensure synergies, the national intellectual property office should be established under a ministry that is actually involved in activities related to intellectual property. For example, the Kenya Intellectual Property Institute is a department under the Kenyan Ministry of Trade and Industry. The Ethiopian Intellectual Property Office is a unit of the Ethiopian Science and Technology Agency. Uganda may wish to consider comparable institutional arrangements.

### ... as well as in its domestic intellectual property laws.

At its current stage of technological development, it appears realistic for Uganda to aspire to improve, in the short and medium term, its capacity in incremental innovation, in particular in those areas identified by the government as investment priorities (i.e. agriculture/agribusiness, education, ICTs and health). Therefore, the main objective of domestic intellectual property laws should be to reach a stage of technology development where stakeholders (industry and scientists, but also the general public) are in a position to better absorb knowledge and use it in their particular environment.

By granting their holders exclusive rights over the use of technology products in a country's territory, IPRs provide important incentives to domestic stakeholders to engage in technology development as well as to foreign investors to make their technologies available in the domestic market. At the same time, however, IPRs, due to their exclusive character, may prevent domestic firms (and possibly researchers) from using technology-relevant information needed for technological learning, as well as for incremental and follow-on innovation. Countries at an early stage of technological development, like Uganda, depend to a great extent on informal means of technology transfer, i.e. the acquisition of technologies through imitation, reverse engineering and, at a more advanced stage, adaptation to local conditions. Accordingly, Uganda's 2007 Communication to the WTO Council for TRIPS of Priority Needs for Technical and Financial Cooperation emphasizes the importance of the public domain as a source of knowledgebuilding and technology absorption.

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At early stages of development, exclusive rights in technology information, which in Uganda are mostly held by foreigners, render the use of informal means of technology transfer more difficult or even entirely impossible, thus complicating the creation of domestic technological expertise. For developing countries and especially least developed countries like Uganda, it is therefore essential to adopt levels of intellectual property protection that are reflective of their actual level of development and needs for technological learning. This means that Uganda's intellectual property system should seek to accommodate domestic dependence on reverse engineering. The domestic intellectual property system should seek to strike an appropriate balance between incentives for innovators and avenues for competitors to access technology-relevant information. In striking this balance, intellectual property legislation should take account of the importance of the public domain for technological learning and incremental innovation.

### The patentability criteria should enable the preservation of a robust public domain.

In order to be patentable, an invention has to be new (i.e. unavailable to the public), include an inventive step (i.e. be nonobvious to a person skilled in the art) and be ready for industrial application (i.e. manufactured or used in any commercial activity, including agriculture). By determining the criteria under which an invention is patentable, a country may exert a significant influence on the important question of where to draw the line between exclusive rights and the public domain. In order to preserve a robust public domain, a number of amendments should be made to the current (2009) Industrial Property Bill.

#### Recommendation 3: Design of patentability criteria.

(a) The provision on the inventive step could be amended to specify that the assessment of non-obviousness of the invention does not need to be based on a local person skilled in the art, but rather on skills existing anywhere in the world, including in Organization for Economic Cooperation and Development (OECD) countries. Importantly, the provision may be interpreted as encompassing prior art that is not contained in a single document, but spread across a variety of sources (multiple prior art references), following a tightening of the nonobviousness standard in the United States; [Section 11 of the Industrial Property Bill]

(b) In order to maintain researchers' freedom to operate, the provision on industrial application may be interpreted as excluding from patentability research tools for which no particular use has been specified in a patent application; this would correspond to the practice by the European Patent Office of denying patents on research tools that are claimed for an undefined variety of different uses;

#### [Section 12 of the Industrial Property Bill]

(c) The above interpretations of the inventive step and industrial application standard should be included, in express form, in national patent examination guidelines or regulations, or even directly in the Industrial Property Bill. This would take account of the fact that for applications under the Patent Cooperation Treaty, the International Preliminary Examination Report is carried out by foreign Patent Cooperation Treaty examiners, who have to rely on written documentation. The language used in the current version of the Industrial Property Bill on inventive step and industrial application does not reveal how these requirements should be applied to a concrete case.

[Sections 11 and 12 of the Industrial Property Bill, patent examination guidelines]

#### In order to make technology transfer provisions in domestic laws more effective, an inventor should be required to show compliance with such provisions in the patent application.

Establishing a link between the obligations of a patent applicant under the Industrial Property Bill to disclose certain information and the technology transfer provisions under the National Environment Regulations and the Investment Code would provide an incentive to patent applicants to comply with these technology transfer provisions.

### Recommendation 4: Provide inter-policy coherence between patent and other policies.

(a) In the Industrial Property Bill, the provision on disclosure of origin and prior informed consent in patent applications based on genetic resources or traditional knowledge should be amended to expressly require the showing, by the patent applicant, of compliance with technology transfer requirements under the National Environment Regulations;

[Section 21 of the Industrial Property Bill; section 20(e) of the National Environment Regulations]

(b) A new provision should be added under the Industrial Property Bill to require the patent applicant to show compliance with the technology transfer provisions under the Investment Code.

[Section 20 of the National Environment Regulations; section 30 of the Investment Code]

# Patent applicants should be obliged to disclose the best mode for carrying out the invention to enable technological learning.

The traditional justification for granting exclusive rights rests upon the assumption that in exchange for the grant, society should benefit from the new technology incorporated in the invention. Many areas of today's technologies are so complex that patent applications alone are often not comprehensible, because they are limited to a description of the key features of the invention without explaining the way in which the invention is best carried out. Such explanations are of essential importance for countries engaged in the technological learning process. Making them mandatory would also correspond to Uganda's 2007 Communication to the TRIPS Council of Priority Needs for Technical and Financial Cooperation, where the government emphasized the need for the development of a patent information service to support innovation and technology transfer. Clearly drafted patent applications could play an important role in this respect.

### Recommendation 5: Best mode disclosure obligation in patent applications.

Patent applicants should be required to disclose in their applications the best mode for carrying out the invention known at the time of filing the application, as expressly permitted under the TRIPS Agreement. This is an important contribution to helping local innovators and researchers fully understand the technology claimed in the patent.

[Section 39(a) of the Industrial Property Bill]

# Scientists and researchers need to be able to use a patented invention to gain new knowledge and to develop new products.

While the availability of exclusive rights provides an important incentive for inventors to engage in inventive activity, the privatization of certain substances and processes must not at the same time hinder scientific and technological progress. Scientists involved in both basic and commercial research must experiment "on" a patented invention to gain new knowledge on the subject matter itself. They also need to use patented inventions as research tools (i.e. research "with" existing inventions) in order to develop new products and thus contribute to scientific and technological progress.

### Recommendation 6: Use of patented inventions by researchers.

(a) In order to prevent misunderstandings regarding its scope, the current research exception (experiments "on" the

patented invention) should be amended, to the effect that the generation of new knowledge on the patented product should be the overall and preponderant purpose of the experiment. The generation of revenue may constitute a secondary purpose; *[Section 44(a) of the Industrial Property Bill]* 

(b) The patented invention should also be available for those who intend to use it as a research tool to develop new products that are independent of the originally patented product (i.e. experiments "with" the patented invention). Following the example of Swiss patent law, such a result should not be achieved by invoking the experimental use exemption. Instead, a separate provision should be established within the Industrial Property Bill, subjecting patented research tools to a license of right. Accordingly, patentees should receive remuneration from others for using the tool, but should not be allowed to prevent access to protected research tools.

### Small-scale inventors in Uganda need appropriate incentives, either through utility models ...

As opposed to patents, utility models are generally used to protect inventions that do not meet the "inventive step" test under patent law, but that nevertheless contribute a new and useful product to society. As opposed to patents, the TRIPS Agreement contains no minimum standards on the protection of utility models, leaving this up to members' entire discretion. Under the current version of the Industrial Property Bill, the novelty standard applicable to utility models (i.e. in sections 69(1) and 68(1)) does not seem to take account of the rather low level of local technological know-how. The 10-year term of protection, by contrast, appears appropriate to provide incentives to local innovators to engage in potentially costly and time-consuming research and development.

#### Recommendation 7: Tailor the novelty standard under utility model protection to the capacities and needs of local inventors.

With a view to promoting incremental domestic innovators, the novelty standard under utility law should refer to domestic novelty, as opposed to the novelty standard under patent law. [Sections 69(1), 68(1) of the Industrial Property Bill]

#### ... or through a sui generis "use and pay" regime.

While the utility model system may be considered as providing appropriate incentives to incremental innovators, it should be acknowledged that due to their exclusive rights character, utility models could raise concerns comparable to those under patent law, i.e. regarding the blocking effects on follow-on innovation and competition. An alternative way of promoting incremental innovation is through the establishment of a regime of compensatory liability, or "use and pay", which in principle authorizes third parties to use the invention in order to develop improvements, but obliges them to pay compensation for such use to the inventor.

Considering that the introduction of a use and pay regime would generate learning costs in the beginning, such as the establishment of a system for the determination of the royalty payments (through arbitration and a supervisory court), the government could consider the limited introduction of a use and pay regime for uses of traditional knowledge and genetic resources only, thus enabling the provider communities to receive remuneration for the use of their know-how and biodiversity. This may improve domestic capacities in agricultural technologies, agribusiness and pharmaceuticals, which are among the government's investment priority areas.

**Recommendation 8: Introduce a "use and pay" regime for applications of traditional knowledge and genetic resources.** Under such a regime, the small-scale innovator has three separate rights:

(a) The first right is the right to prevent second comers, for a certain period of time, e.g. 20 years, from wholesale imitations of the right owner's product;

(b) Under the second right conferred, the incremental innovator may claim reasonable compensation from any party that uses the protected innovation for any value-adding improvements, for a specified period of time (e.g. 20 years). The original innovator would be prevented from blocking access by competitors to his innovation, unless wholesale duplication is sought. The right to compensation could be preceded by a much briefer period of market exclusivity for the inventor (e.g. one or two years), in order to establish his brand. Suggested royalty rates range between 3 and 9 per cent of the sales revenue of the improved product. Disputes over the amount of royalties to be paid to the incremental innovator should be settled through mediation or arbitration;

(c) The third right would entitle the original inventor, for a certain period of time, to make use of a second comer's technical improvements, in exchange for the payment of reasonable compensation to the latter. This right could be just as long as the second right (e.g. 20 years).

### Local small-scale innovators can also be promoted through trade secrets protection.

Trade secrets protection may also have some potential for the promotion of incremental innovation and technology transfer, as it enables technological learning through reverse engineering by honest commercial means, while at the same time providing protection to the original innovator. The fact that under trade secrets law, independent development of the protected information or its discovery through reverse engineering constitutes a defence to trade secrets infringement claims puts much importance on the allocation of the burden of proof in litigation. The Trade Secrets Protection Act is silent in this regard and should be modified to include an express rule on the burden of proof under trade secrets infringement claims.

### Recommendation No. 9: How to allocate of the burden of proof in trade secrets infringement litigation.

The Trade Secrets Protection Act should provide that a prima facie case of trade secrets misappropriation is established through a demonstration by the claimant (i.e. the owner of the trade secret) of the use of the protected information by the defendant. The defendant may rebut the presumption by claiming independent development of the protected information. In addition to this general assertion, the defendant has to persuade the court that in the particular case, he effectively arrived at the protected information through independent means. If he fails to do so, the prima facie presumption of misappropriation as established by the claimant should remain valid, resulting in a finding of trade secrets infringement. *[Trade Secrets Protection Act, 2009]* 

#### Another important means to transfer technology is through the licensing of intellectual property, provided the terms do not contain unjustified restrictions ...

Both the Investment Code and the Industrial Property Bill contain safeguards against the use of restrictive terms in licensing contracts, which would deny technology spillovers from the (mostly foreign) licensor to the domestic licensee. The Industrial Property Bill for this purpose contains a list of licensing practices that are to be considered as unjustified restrictions that may trigger the refusal by the registrar to register the entire licensing contract. In this list, restrictions based on the licensor's industrial property rights are broadly exempted from the notion of uniustified restrictions. These exemptions appear too broad and should be qualified. While a licensee cannot expect to have access to technologies and expertise that is not included in a licensing agreement, he should have the right to use the intellectual property that was actually licensed to build his own expertise, in line with article 7 of the TRIPS Agreement and section 30 of the Investment Code.

### Recommendation 10: Ensure licensed intellectual property may be used for technological learning.

The provisions in the Industrial Property Bill dealing with restrictive terms in licensing contracts should be amended to include as unjustified those restrictions imposed on the use by the licensee of IPRs that are part of a licensing contract. Exemptions in this regard should be limited to those IPRs that are not included in the licensing agreement.

[Sections 55(2)(s) and (x) of the Industrial Property Bill]

# ... and provided the licensing agreement does not promote certain anti-competitive practices and abuse of IPRs.

The TRIPS Agreement authorizes members to specify in their legislation licensing practices that may in particular cases constitute an abuse of IPRs having an adverse effect on competition in the relevant market. The Industrial Property Bill fails to provide for a comparable provision, and for the definition of a number of important anti-competitive practices listed in the TRIPS Agreement (i.e. article 40.2), as well as the important notion of intellectual property abuse, which the TRIPS Agreement does not define.

### Recommendation 11: Provide for definitions of intellectual property abuse and certain anti-competitive practices.

Both the Industrial Property Bill and the Ugandan Draft Competition Act (2004 version) should contain a definition of intellectual property abuse, as well as definitions of exclusive grantback conditions and conditions preventing challenges to validity in licensing agreements. This may facilitate the screening of prohibited terms in technology licensing contracts.

#### II. Intellectual Property and Access to Medicines

The goal in the National Drug Policy of encouraging locally produced and generic medicines should translate into the promotion of domestic manufacturers through measures in the area of government procurement ...

Uganda as a non-party to the WTO Agreement on Government Procurement is not bound to extend to foreign drug suppliers treatment no less favourable than it accords domestic producers.

### Recommendation 12: Accord priority to local producers in medicines procurement.

Provided local producers are capable of manufacturing high quality medicines at competitive prices, government procurement agencies, such as the Ministry of Health and the Joint Clinical Research Centre, should give preference to local producers.

#### ... as well as in the area of drugs regulation ...

Effective drug regulation following good governance principles and compliance with regulatory standards play a key role in the promotion of domestic high quality medicines. WHO considers drug registration procedures before the Ugandan National Drug Authority (NDA) to be speedy, and the technical staff sufficiently skilled and less subject to personnel fluctuations than in comparable developing countries. Nevertheless, WHO has considered NDA to be underfunded, despite very encouraging developments over the past years concerning the amounts of funds received by NDA as well as important increases of internally generated revenue.

### Recommendation 13: Ensure independent funding of the Ugandan NDA.

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It is essential for NDA to continue receiving the bulk of its revenue from service fees, making it independent from foreign donor or government funding. An important element in these efforts is continuous consultation with stakeholders to ensure that fees, while supporting NDA's activities, do not overburden domestic companies.

### ... and should also be reflected in the country's legislative framework on intellectual property.

Countries seeking to establish domestic technological capacity in pharmaceutical sector should empower domestic the stakeholders to reverse engineer and to be able to benefit from a relatively broad public domain, which may be promoted through the full use of the flexibilities available under the TRIPS Agreement. For these reasons, the following recommendations on Uganda's intellectual property legislation will be guided by the understanding that a substantial amount of operating space should maintained for the producers of be generic pharmaceuticals, enabling both affordable drug prices and domestic technological learning. While the need to protect and encourage innovation is paramount, considerations related to the transfer and dissemination of technology, the protection of public interests and the promotion of a pro-competitive environment are important considerations for making the system relevant and appropriate in an environment like Uganda's.

### The provision on the "mailbox" for pharmaceutical patent applications should be amended.

The Industrial Property Bill has taken advantage of the 2016 transition period for the introduction of pharmaceutical product patents and clinical test data protection. In order to accommodate the interests of applicants for pharmaceutical patents, the bill has also implemented a "mailbox" provision.

According to that provision, members that do not make available patent protection for pharmaceutical products nevertheless have to provide a system under which patent applications can be filed and kept ("mailbox") during the transition period. Upon termination of the transition period, all applications in the mailbox will then have to be examined, under the premise that the patentability criteria have to be considered as if these criteria were being applied on the date of filing the application. For generic producers, this may have important negative implications, as products they have used during the transition period may become subject to a patent once the transition period expires in 2016. Under the TRIPS Agreement (article 70.8), members such as Uganda – which as of the date of entry into force of the WTO Agreement provided patent protection to pharmaceutical products but later suspended such protection on the basis of the LDC transition period - are not obligated to implement the mailbox. In this respect, the Industrial Property Bill goes beyond what Uganda is required to do under the TRIPS Agreement.

### Recommendation No. 14: Abolish the mailbox provision in the Industrial Property Bill

The government should consider amending subsections 13 and 14 of section 28 of the Industrial Property Bill to the effect that applications for pharmaceutical product patents may only be filed after 1 January 2016.

[Sections 8(3)(f), 28(13), (14) of the Industrial Property Bill]

### The effectiveness of third party patent opposition procedures needs to be improved.

Pre-grant patent opposition procedures before the intellectual property office may be an efficient means to avoid costly postgrant infringement litigation, to the extent that a given invention does not meet the national patentability criteria. However, this presupposes a certain degree of scientific capacity in the intellectual property office, which is of key importance also in the context of technology transfer (see above, recommendation 2a). In addition, it seems important to admit third party oppositions in the context of African Regional Intellectual Property Organization (ARIPO) patent examinations, in view of the fact that for the time being, all patent applications filed in Uganda are exclusively examined by ARIPO.

### Recommendation 15: Enhance the effectiveness of third party patent oppositions.

(a) The opposition procedure in the Industrial Property Bill could best unfold its beneficial effect if the national intellectual property office were provided the technical capacity to examine the substance of the opposition before forwarding the patent application to ARIPO. This presupposes a thorough reform of URSB, enabling it to benefit from scientific know-how available in other institutions such as UNCST and UIRI (see also recommendation 2);

[Section 28(7) of the Industrial Property Bill]

(b) In addition, the Harare Protocol should be amended to take account of third party oppositions. The government should consult with the governments of other East African Community (EAC) partner States that also provide third party oppositions (especially Burundi and the United Republic of Tanzania) to what extent an amendment of the Harare Protocol seems feasible.

### The patentability of natural substances should be expressly addressed.

The Industrial Property Bill leaves open the question to what extent natural substances may be regarded as inventions or rather as non-patentable discoveries. This question has important implications for generic pharmaceutical producers as medicaments may entirely or partially consist of biological substances, including extractions from plants, algae and human proteins, and the results of genetic engineering. Considering the reliance of the Ugandan health system on generic producers, domestic patent law should allow, to the greatest possible extent, for the reverse engineering and subsequent production of drugs that are based on natural substances.

### Recommendation 16: Exclude natural substances as such from patentability.

The Industrial Property Bill could be amended to exclude from the notion of "invention" substances as they exist in nature or that have been isolated from nature in their original form. This would not exclude the patentability of the process used for isolating the substance. Such a process patent would not prevent competitors from isolating the same substance using a different, non-patented process.

[Section 8 of the Industrial Property Bill]

#### Local innovation is often limited to small-scale improvements and will hardly benefit from new use patents.

In the area of pharmaceuticals, the same substance may sometimes be used to treat different illnesses. For example, the AZT drug Retrovir, previously used to combat cancer, was later found to also be effective in treating HIV/AIDS. The question arises to what extent a substance that has been patented for a particular use, should again be patentable upon the discovery of a second, third (or more) use. The patentability of new uses may provide important incentives for inventors to engage in the discovery of new uses. On the other hand, discovering and commercially applying a new use usually presupposes the possibility to use the already patented underlying substance or process, which may be dependent on the authorization from the patent holder. The Industrial Property Bill addresses this problem through a broad research exemption (see recommendation 6) and the express rule that the owner of a new use patent may use his invention without prior authorization from the owner of the underlying patent, from which the new use has been developed (section 38(1)(c)). However, both provisions are premised on the

condition that the newly discovered use actually meets the criteria of patentability:

- The research exemption does authorize research on the original substance for the purpose of generating new knowledge, but if the result of such research is limited to small-scale improvements, which do not meet the novelty or inventive step criteria, the improvement product would arguably fall within the claims of the original patent and its marketing could be prevented;
- The express authorization to benefit from new uses without the consent of the owner of the underlying patent only applies to the extent that the new use itself meets the patentability criteria. Small-scale, follow-on improvements to patented medicinal uses could still be prevented by the holder of a new use patent under this provision.

Ugandan innovators may not primarily be involved in breakthrough innovation, which would meet the patentability requirement of inventive step. They are more likely to benefit from the use and pay regime suggested under recommendation 8, where the first innovator can only claim compensation, but may not prevent the use of his invention for any value adding follow-on improvements, even where these do not meet the patentability criteria. In order to give the first innovator a chance to establish his brand in the market, the right to claim compensation may be preceded by a short exclusive right, e.g. two years. Such a scheme may prove particularly useful in areas where domestic innovators have developed considerable expertise, i.e. in generating new applications of traditional knowledge and genetic resources.

## Recommendation 17: Exempt applications of traditional knowledge and genetic resources from new use patents and introduce a use and pay regime.

As suggested under recommendation 8, the government may consider the limited introduction of a use and pay regime for (pharmaceutical and other) uses of traditional knowledge and genetic resources, thus enabling the provider communities to receive remuneration for the use of their know-how and biodiversity. This may improve domestic capacities in agricultural technologies, agribusiness and pharmaceuticals, which are among the government's investment priority areas. [Section 38(1)(c) of the Industrial Property Bill]

#### The patentability of product derivatives may have blocking effects on the generic marketing of the original substance.

While the new use issue relates to several uses of identical chemical entities, derivatives are products that are of a slightly different chemical structure than the originally patented product. Although legally speaking, a patent granted for variations would not hinder generic producers from using the original substance under an expired first patent, access might still be blocked by the new patent, as in infringement actions judges might face difficulties in deciding on the exact scope of the original and the new patent claims. Therefore, time-consuming infringement litigation can block commercialization of the generic copy of the original product. The Industrial Property Bill is silent on this issue. Considering the practical importance of this issue, it seems appropriate for policymakers to decide whether product derivatives merit patent protection. In this respect, foreign approaches, such as in India and the United States, may provide some important guidance.

### Recommendation 18: Provide for rules on the patenting of pharmaceutical product derivatives.

(a) The Industrial Property Bill or regulations (where available) should provide that structural similarities between a known and a new pharmaceutical substance create a presumption of lack of invention, novelty or inventive step. The burden of proof would then lie on the patent applicant to demonstrate significantly superior properties with regard to the efficacy of the variant, in which case a patent would have to be granted;

(b) Those product derivatives that do not meet the above criterion of significantly superior properties may nevertheless be awarded some form of protection in order to encourage local incremental innovation. The most appropriate approach seems to be a use and pay model, which provides incentives for incremental innovation without blocking access by competitors to the modified substance for improvement purposes.

#### If parallel imports of medicines are to be effective, the same rule must be adopted under patent, copyright and trademark law.

Considering Uganda's increasing dependence on the parallel importation of patented foreign pharmaceutical substances (including active pharmaceutical ingredients for successful local producers), the government's choice of legitimizing parallel imports under patent law seems appropriate. However, parallel importation also needs to be admitted under domestic copyright and trademark law, otherwise the owner of an originator product that is patented, trademarked and copyrighted (to the extent the pharmaceutical description of the product is copyrightable under domestic law) in Uganda may block the parallel importation of branded originator products on the basis of trademark and potentially copyright law.

The reference to "importation into Uganda" of patented products in the provision on parallel imports in the Industrial Property Bill seems superfluous. The legitimacy of parallel imports can only be based on the first sale in the market, but not on the act of importation. Without this reference, the provision provides a clear rule of international patent exhaustion. Recommendation 19: Provide coherence among domestic exhaustion regimes.

(a) In harmony with the Industrial Property Bill, the 2006 Copyright Act should be amended to admit the parallel importation of copyrighted works from any country in the world where adequate copyright protection is provided. The same approach should be pursued under the new trademark law that is currently being discussed;

[Section 43(2), Industrial Property Bill; section 32(1)(a) of the Copyright and Neighbouring Rights Act, 2006]

(b) In the provision on parallel imports in the Industrial Property Bill, the reference to "importation into Uganda" should be deleted, as it adds no new substance but only creates confusion.

[Section 43(2), Industrial Property Bill]

### The rules on compulsory licensing are not fully TRIPS-compliant ...

The Industrial Property Bill contains a number of provisions on compulsory licensing, not all of which meet the minimum requirements mandated under the TRIPS Agreement. By 2013, these rules should be made TRIPS-compliant.

### Recommendation 20: Make compulsory licensing rules TRIPS-compliant.

(a) The bill should be brought in line with the minimum standards under article 31(h) of the TRIPS Agreement by 1 July 2013, and entitle the right holder to claim, in principle, adequate remuneration in case of a government use license. However, this does not apply to the case of pharmaceutical products before 2016;

[Section 66(3), Industrial Property Bill]

(b) By 1 July 2013, any decision to grant a compulsory or government use license should be made subject to independent review by higher authorities, in order to meet the minimum standard under article 31(i) of the TRIPS Agreement. Such authorities may be a (higher instance) court or a more senior government agency. Recourse by the patent holder to injunctive relief may be excluded under the conditions spelled out in the TRIPS Agreement (article 44.2);

(c) By 1 July 2013, any decision regarding the amount of remuneration to be paid to the patent holder for the non-voluntary use of his/her invention should be subject to independent review by higher authorities, in order to meet the minimum standard under article 31(j) of the TRIPS Agreement.

### ... nor do they take full advantage of flexibilities provided under TRIPS.

The Industrial Property Bill should also be amended in order to facilitate the use of compulsory licensing as an effective policy tool.

### Recommendation 21: Make full use of TRIPS flexibilities in compulsory licensing.

(a) The Industrial Property Bill should be amended to include a reference to a maximum period of negotiations with the right holder before granting a compulsory license. Alternatively, this could be done under a set of administrative regulations. The general period could be of up to six months (following a parallel provision in Burundi's Draft Patents Act of 2007), with an exception in the area of essential, life- saving drugs of a maximum 45 days (in line with a parallel provision in the United Republic of Tanzania's Draft Bill for an Act on Industrial Property Rights for Zanzibar of 2008);

[Section 60(1)(a) of the Industrial Property Bill or administrative regulations]

(b) The bill should be amended to provide that when using the draft article 31bis TRIPS system as an importing country, the patent holder in Uganda does not need to be remunerated, to the extent that adequate remuneration has already been paid to the patent holder in the exporting country; [Section 61(2)(e) of the Industrial Property Bill] (c) The bill should be amended to include the possibility of (speedier) administrative (as opposed to more time-consuming judicial) grants of compulsory licenses for private third parties acting on their own behalf and account. The ministry primarily involved in the issue that is subjected to the compulsory license should be authorized to issue the compulsory license; in the area of pharmaceuticals, this should be the Ministry of Health; [Section 61(1) of the Industrial Property Bill]

(d) On re-exportations of pharmaceuticals under the WTO 30 August 2003 Waiver Decision, the bill should not only refer to the Common Market of Eastern and Southern Africa, but also to the partner States of the EAC. This is in the interest of both access to medicines in the EAC and enhanced trade opportunities for local producers in Uganda. It is also in line with the establishment of an EAC-wide customs union.

[Section 102(8) of the Industrial Property Bill]

# The introduction of protection for pharmaceutical test data implements an obligation under the TRIPS Agreement, which may be interpreted in a way conducive to generic producers.

The Trade Secrets Protection Act (2009) provides an obligation to protect pharmaceutical and other test data against "unfair commercial use".

### Recommendation 22: The protection of pharmaceutical test data.

The above obligation under the Trade Secrets Protection Act 2009 should be interpreted as allowing the drug regulatory authority to rely, in the course of approving generics, on the data previously submitted by the originator company. This approach is supported by existing drug regulatory practice in Uganda.

[Section 11(2) of the Trade Secrets Protection Act, 2009; section 2 of the Guidelines on Registration of Pharmaceutical Drugs for Human Use in Uganda (revised August 2001)]

The Counterfeit Goods Bill of 2009 applies broadly to all intellectual property categories, which may have negative implications for generic producers. In "counterfeiting" addition. the definition of in avoid medicines should be made clearer to misunderstandings.

The bill provides criminal sanctions in case of patent infringements in excess of the minimum standards of TRIPS and legal practice in many OECD countries. As opposed to trademark and copyright infringements, it is not always obvious for a company to know whether, by using certain materials, it may be breaching an existing patent. Often, the exact scope of pharmaceutical patents is unclear and can only be determined through expert investigation. The threat of criminal fines and imprisonment may have a deterring effect on generic producers' activities. As a fallback option, the definition of "counterfeiting", after much controversy, has been amended to make clear that it does not include correctly labelled generic medicines. However, the limitation of this definition to mislabelled products could be expressed in clearer terms, to avoid misinterpretation and confusion.

#### Recommendation 23: Amend the Counterfeit Goods Bill.

(a) The most appropriate amendment to the bill would be the exclusion of patents from its scope, limiting it to trademarks and copyrights only. In line with the TRIPS Agreement, criminal sanctions should only apply to cases of wilful trademark counterfeiting and copyright piracy on a commercial scale;

(b) To the extent a pharmaceutical product is patented (especially as of 2016), the right holder should be provided with the general remedies available under the TRIPS Agreement to address patent infringements. As opposed to remedies available in the case of trademark counterfeiting, these remedies do not include criminal measures (i.e. fines and imprisonment), but are limited to injunctions, the payment of damages and certain provisional measures including potentially the destruction of the infringing goods (articles 44–46, 50, TRIPS Agreement);

(c) In case the above amendment is not politically feasible, the definition of "counterfeiting" in the context of medicines should be amended:

(aa) Delete the term "includes". This would clarify that the term "counterfeiting" does not include the unauthorized manufacturing, producing, packaging, re-packaging, labelling or making of pharmaceutical products, but is limited to the deliberate and fraudulent mislabelling of medicines;

(bb) In addition, a sentence could be added, stating that in the case of medicines, the other subparagraphs do not apply;

(cc) The same definition should make clear that the term "medicines" is not limited to finished products, but should include all elements required to make a drug, i.e. the active

pharmaceutical ingredients and the excipients. In addition, the definition should encompass other products that are important for promoting access to medicines, such as vaccines, diagnostic kits and medical equipment;

[Section 2 (c) of the Counterfeit Goods Bill]

(d) Section 3 of the bill should be amended, stating that in the case of medicines counterfeiting, the leading agency to administer the act is the National Drug Authority.

#### III. Intellectual Property and Access to Textbooks

# Improving access to textbooks in Uganda requires finding the appropriate balance between improved copyright enforcement on the one hand ...

The current lack of copyright enforcement should be addressed by the government, not only to meet its TRIPS obligations after 1 July 2013, but equally in the interest of its domestic creators and publishers. With respect to the latter, it is important to note that IPRs are private rights and their enforcement thus mainly falls under the responsibility of the right owners. The state, however, needs to have the capacity to respond to rights holders' requests for copyright enforcement.

#### Recommendation 24: Provide for training and capacitybuilding on copyright enforcement.

(a) Such activities should above all target rights holders and domestic lawyers, in order to clarify their rights and the means to enforce them;

(b) Enforcement authorities should also benefit from training activities and possibly increased budgets to hire more staff;

(c) Technical and financial support for these activities should be requested from OECD countries. WIPO could also be approached in this respect.

#### ... and a modern copyright law that takes account of the actual needs on the ground, including the digital environment, on the other hand.

The ultimate purpose of copyright law is the promotion of creativity. Creativity builds upon existing knowledge and the possibility to access knowledge-relevant information. This explains the importance of detailed provisions on copyright limitations and exceptions. The latter, however, are vague under the 2006 Copyright Act and especially neglect the digital environment. The WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty authorize countries to devise new limitations and exceptions specific to the digital environment.

#### Through the use of various types of open source licenses, rights holders and publishers may promote access to copyrighted works to the extent chosen by them.

Under an open source license, the copyright holder uses its copyright to determine the conditions under which the work may be used by third parties. As explained in the main report, under the Creative Commons movement, there are six main types of open license, which allow, in various degrees, the free use of copyrighted works, while preserving the right owners ultimate control, if he/she so wishes.

### Recommendation 25: Promote the use of open source/Creative Commons licenses.

(a) Publishers are strongly encouraged to use open source licenses, such as the models offered by Creative Commons, to provide bulk access to textbooks. The experience of foreign and domestic publishers with open licensing schemes should be studied, and the choice of the appropriate form of license should be made in close consultation with the Ministry of Education; (b) Publishers should promote the urgent development of a national Creative Commons license, possibly in collaboration with other publishers in the EAC partner States.

# The copyright exceptions under the 2006 Copyright Act should be clearer on the scope of permitted activities.

The Berne Convention, the TRIPS Agreement and related state practice recognize various exceptions to copyright, such as exceptions for the purpose of teaching, private personal use, use by libraries, making quotations and news reporting. Uganda's Copyright Act seeks to reproduce these exceptions, but is often not clear on the scope of authorized activities.

### Recommendation 26: Provide for clearer language in the provisions on copyright exceptions.

(a) The teaching exception should more clearly refer to "reproduction" of copyrighted materials, including digital copies; [Section 15(1)(c) of the Copyright Act]

b) The teaching exception should directly authorize the reproduction, to a certain extent, of teaching materials (inter alia textbooks) by the students themselves;

[Section 15(1)(c) of the Copyright Act]

c) Digital copies produced at schools, while accessible for free to enrolled students, could be made to contain software that allows just one reproduction, thus preventing further electronic dissemination. The same limitation applies in the case of the private personal use exception and the libraries and educational institutes exception;

#### [Sections 15 (1)(a), 15 (1)(j) of the Copyright Act]

d) The reference to the third prong of the three-step test should be to the "interests of the author of the work" (as opposed to the "rights"), in line with article 13, TRIPS Agreement. In addition, there should be a proviso based on the preambles to the WIPO Internet Treaties, referring to the "larger public interest, particularly education, research and access to information, as reflected in the Berne Convention". [Section 15(1)(j)(ii) of the Copyright Act]

#### In addition to traditional fair use elements, other criteria that better reflect the actual needs in Uganda should be taken into account when examining the extent to which textbooks may be copied.

The question of what portion of a textbook may be copied under an exception cannot be answered in general, but depends on a case-by-case assessment. Thus, the three-step test should be applied in a flexible manner, taking account of the limited purchasing power of Ugandan students and thus authorizing the reproduction of larger parts of textbooks than would be admissible in a developed country context. In order to take into account the rights holders' interests, users should pay photocopy levies, provided copyright enforcement is stepped up in line with our Recommendation 24.

# Recommendation 27: Provide for more flexible criteria to define the extent to which a textbook may be copied under the exceptions.

(a) The teaching exception, the libraries and educational institutes exception, and the private personal use exception should take into account elements such as affordability and availability (either in digital or hard copy version) of the book, and the subject matter of the class at issue;

(b) Since the user of the library generally needs access to the full document, rather than a mere extract, reproductions made by libraries should encompass the entirety of the copyrighted work or textbook. This should also apply to educational institutes as long as making available the textbooks in electronic form and solely on school premises does not affect the overall purchase agreements between the government (or the schools) and the publisher for hard copy textbooks that students may take home. Technological protection measures

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(TPMs) may be used to prevent users from further disseminating electronic copies beyond the library and educational institute context (see Recommendation 26);

(c) To the extent that copies may be made, the law should provide for an obligation by users to pay a levy to the rights owner, ideally represented by an accountable collecting society. Such levies could be funded from a generally applicable flat rate on photocopies, which would have to take account of users' ability to pay.

[Sections 15 (1)(a), 15(1)(c), 15 (1)(j) of the Copyright Act]

#### Regulating the use of technological protection measures constitutes an important element of modern copyright law and is essential in ensuring the effective operation of copyright limitations and exceptions.

Uganda's Copyright Act extends copyright and neighbouring rights to the digital environment. Copyright holders have increasing recourse to TPMs to prevent the illegal mass copying of copyrighted online content, but also to prevent access by users to online materials that is authorized under domestic copyright limitations and exceptions. In addition, users – in order to legally access TPM-protected online information – are often asked to waive the rights available to them under domestic copyright exceptions. To ensure the efficient operation of limitations, copyright exceptions and Ugandan domestic copyright law needs to be reflective of these new realities. One option is to implement the TPM-related provisions of the WIPO Internet Treaties, which enable countries to refuse the support of TPMs to the extent these restrict recourse to domestic copyright limitations and exceptions. The technical difficulty in regulating TPMs is the fact that TPMs may simultaneously prevent both illegal and legal uses of copyright works. The alternative to generally blessing TPMs (even where in contradiction to existing statutory users' rights) is a regime proposed in the literature where users may request the right holder to take down a TPM for

a particular use that meets the requirements of a statutory exception or the fair use doctrine. In the case of denial, the user could seek a declaratory judgment. While this solution has the advantage of preserving copyright limitations and exceptions in the digital area, it could entail considerable transaction costs, as its operation would require the further elaboration of technical details, the building of copyright capacities among local judges and a means to finance users' expenses arising from litigation. Before making any final recommendations in this regard, it is suggested that the issue be subjected to a consultative process among domestic stakeholders.

### Recommendation 28: Implement the WIPO provisions on the use of TPMs.

(a) The government should consider the implementation of articles 11 of the WIPO Copyright Treaty and 18 of the WIPO Performances and Phonograms Treaty to limit the use of TPMs to those cases where the unauthorized use of copyrighted works is not supported by domestic copyright limitations and exceptions;

(b) In a related provision, the copyright limitations and exceptions should be declared to be peremptory, mandatory and non-waivable;

(c) Finally, the government should initiate an open-ended consultative process among stakeholders to discuss the potential in Uganda of a TPM take-down regime, as described above.

#### Considering the importance Uganda has been attaching to its ICT sector, there seems to be an urgent need to address the reverse engineering of computer software, in order to provide legal security to software developers.

ICTs are one of the priority investment areas in Uganda. The reverse engineering of existing software is an essential part of the development of new software. Under the current Copyright Act, it is not clear to what extent such reverse engineering is compatible with copyright protection.

### Recommendation 29: Address the reverse engineering of software.

The Copyright Act should be amended to include a provision on the reverse engineering of software. Such a provision could state that copyright law in principle does not prevent the reverse engineering of computer programs in order to find out more about the concept or idea underlying the software, with a view to independently developing competing software. The provision should make reference to the fundamental express idea/expression dichotomy in copyright law (see, e.g., article 9.2 of the TRIPS Agreement: "Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.").

#### The parallel importation of textbooks could be a means of promoting the availability in Uganda of affordable teaching material. There is also the need to provide coherence between the exhaustion of copyright, patent and trademark law, from an access to medicines perspective.

Some of the textbooks in use in Uganda are also sold in neighbouring countries such as Kenya, Rwanda, Sudan and the United Republic of Tanzania. To the extent that prices charged for these books abroad are lower than in Uganda, the government could initiate the purchase of the books abroad and their subsequent importation into Uganda. As already observed in chapter II of this report, the current Copyright Act does not seem to authorize the parallel importation of copyrighted works. This could also prove problematic in terms of promoting access to medicines, as noted under Recommendation 19.

### Recommendation 30: Authorize the parallel importation of copyrighted works.

In harmony with the Industrial Property Bill, the 2006 Copyright Act should be amended to admit the parallel importation of copyrighted works from any country in the world where adequate copyright protection is provided. The same approach should be pursued under the new trademark law that is currently being discussed.

[Section 32(1)(a) of the Copyright Act]

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#### IV. Conclusion: The Way Forward

#### This report has sought to make recommendations that take account of the actual technology and knowledge situation in Uganda. Now multistakeholder consultations are needed on these recommendations to determine the way forward.

The main thrust of the report is that in order to build incremental domestic capacities, a country like Uganda, showing low levels of technological development, would be well advised to rely on a robust public domain rather than on broad exclusive rights. Due to their better developed levels of technological expertise, foreign competitors would often hold the exclusive rights, thereby making access to essential information and thus technological learning more difficult for local innovators and creators. Under a broad public domain, local innovators may more easily access the information they need to develop incremental technological capacity. In this context, it has to be acknowledged that a broad public domain potentially benefits everybody, including powerful such foreian competitors, and that local innovators in circumstances might see less incentive to engage in costly research and development. However, the problem of unequal competitive strengths would persist also in the case of a weak public domain. The difference is that under a well-developed public domain, the local innovator would have better access to information, and even where he is driven out of the market, the public would benefit via a more competitive environment that would finally benefit all consumers. This is particularly relevant in the access to medicines context.

#### Recommendation 31: The way forward.

Acknowledging the above concerns with the public domain approach, our last recommendation is to establish an interministerial body to consider carefully the recommendations in this report in open-ended consultations with domestic stakeholders and experts.