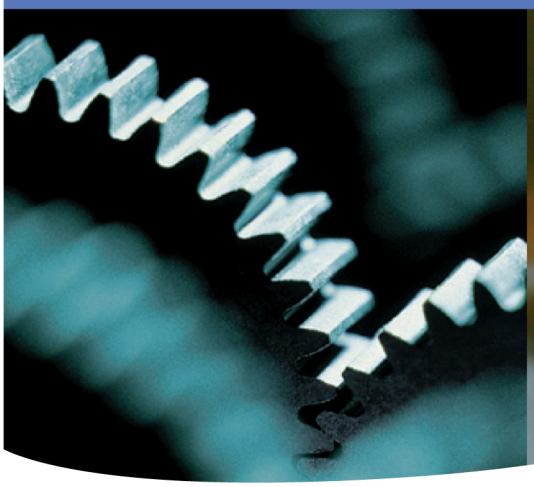
UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

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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Note

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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.[1]

A key component of the project is the preparation of country-specific *Development Dimensions of Intellectual Property (DDIP) Reports*, which seek to assist developing countries and least developed countries (LDCs) 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.

Supachai Panitchpakdi
Secretary-General of UNCTAD

[1] Activities under the project, including the preparation of the present report, were funded by the United Kingdom's Department for International Development.

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 comprised of Sandy Harnisch and Achal Prabhala. In addition, this report benefited from a peer review meeting with domestic stakeholders at Kampala in June 2009, conducted by a team comprising Pedro Roffe, UNCTAD Senior External Advisor and Senior Fellow, ICTSD, and Christoph Spennemann, UNCTAD.

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; Dr. 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.

Abbreviations and Acronyms

API	Active pharmaceutical ingredients
ARIPO	African Regional Intellectual Property Organization
ARV	Anti-retroviral
Bio-Earn	East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development
CISAC	International Confederation of Societies of Authors and Composers
COMESA	Common Market for Eastern and Southern Africa
DDIP	Development Dimensions of Intellectual Property
DRA	Drug regulatory authority
EAC	East African Community
EU	European Union
FDI	Foreign direct investment
GDP	Gross domestic product
GMP	Good manufacturing practice
ICT	Information and communications technology
ICTSD	International Centre for Trade and Sustainable Development
IPR	Intellectual property right
JCRC	Joint Clinical Research Centre (Uganda)
LDC	Least developed country
MoH	Ministry of Health (Uganda)
MSI	Millennium Science Initiative (Uganda)
MTTI	Ministry of Tourism, Trade and Industry (Uganda)
NABOTU	National Book Trust of Uganda
NDA	National Drug Authority (Uganda)
OECD	Organization for Economic Cooperation and Development
PCT	Patent Cooperation Treaty
R&D	Research and development
TPMs	Technological protection measures
TRIPS	Trade-related aspects of intellectual property rights
UAC	Uganda AIDS Commission
UIA	Uganda Investment Authority
UIRI	Uganda Industrial Research Institute
ULRC	Uganda Law Reform Commission
UNCST	Uganda National Council for Science and Technology
UNDP	United Nations Development Programme
URSB	Uganda Registration Services Bureau
WCT	WIPO Copyright Treaty
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WPPT	WIPO Performances and Phonograms Treaty
WTO	World Trade Organization

Background: the Terms of Reference, the Process and the Main Orientation of the Report

The present DDIP Report for Uganda was prepared in response to a request submitted to UNCTAD in 2008 by Uganda's Ministry of Tourism, Trade and Industry (MTTI). Against the background of previous work carried out by ICTSD and SAANA Consulting,[ii] the 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:

i. Access to technology transfer;
ii. Access to medicines (patent laws and test data protection);
iii. 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 was guided by the desire to make recommendations that respond to the situation currently prevailing in the country. For this reason, the DDIP work was not limited to deskwork, but was based on a series of interviews and consultations conducted with domestic stakeholders in Kampala in May of 2008, as arranged by the 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 the MTTI.

In order to assist in the DDIP interviews, UNCTAD contracted a consultant (Professor Ruth Okediji, University of Minnesota School of Law) to develop a methodology for UNCTAD's DDIP activities. This methodology, which may be applied flexibly to various beneficiary countries, is designed to provide a framework for analyses conducted by UNCTAD's fact-finding field missions to (i) help developing countries and LDCs in identifying critical policy issues relevant to the use of intellectual property to effectively leverage development prospects within regulatory frameworks reflective of specific socio-economic and cultural conditions; and (ii) in the formulation of medium- to long-term recommendations on how developing countries and LDC governments could make their intellectual property frameworks more coherent and transparent, with a view to making intellectual property protection consistent with the countries' identified economic and human development goals.

In collaboration with the MTTI, UNCTAD established a list of interview partners from government offices, the private sector, academia and civil society, covering all three areas of interest indicated in the DDIP request. The interviews were conducted from 14–21 May 2008 by a team led by the Intellectual Property Team Legal Expert. Names of the interview partners and the dates of the interviews are mentioned in footnotes to this report. The interviews enabled the author to learn more about the factual background surrounding intellectual property policies in Uganda and their interfaces with related public policy areas such as health, education and the promotion of technology transfer. Based on the interviews, UNCTAD prepared a draft *DDIP Report*, which was submitted to stakeholders for written comments in early 2009 and a peer review meeting in Kampala in June 2009.

The *DDIP 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 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.

The main thrust of the report is that, in order to build incremental domestic capacities, a country like Uganda would be well advised to rely on the development of a robust public domain while granting exclusive protection in the form of intellectual property. Under a broad and robust public domain, local innovators may better access the information they need in order to develop incremental technological capacity. In this context, it must be acknowledged that a broad public domain potentially benefits everybody, including powerful foreign competitors, and that local innovators in such circumstances might see less incentive to engage in costly research and development (R&D). 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 if he is driven out of the market, the public would benefit from a more competitive environment that would eventually advantage all consumers. This is particularly relevant in the access to medicines context.

Acknowledging the complexities of the subject matter and the implications to society of the recommendations made herein, UNCTAD and ICTSD encourage the establishment of an inter-ministerial body to consider carefully the contents of this report in open-ended consultations with domestic stakeholders and experts.

The *DDIP Report* and its *Overview* will be made available at http://www.unctad.org/tot-ip and http://www.iprsonline.org.

[ii] See ICTSD (2007). Technical and financial cooperation needs for implementation of the WTO TRIPS Agreement in Uganda: final report of needs assessment diagnostic. Geneva. See also Government of Uganda (2007). Priority needs for technical and financial cooperation: communication from Uganda to the WTO Council for TRIPS. IP/C/W/500. 9 October.

I. Intellectual Property and Technology Transfer

1. Introduction

Despite Uganda being among the fastest growing economies in Africa, with sustained growth rates of an average of 7.8 per cent since 2000,[3] the country was ranked only 154th out of 177 countries on the United Nations Development Programme's (UNDP) Human Development Index in 2007/2008, with a per capita GDP of $1.45.[4] Agriculture remains the dominant sector in Uganda's economy: according to UNCTAD, the agricultural sector contributes over 40 per cent to Uganda's gross domestic product (GDP) and employs 80 per cent of the working population.[5] Reliance on agricultural commodities, combined with infrastructural gaps,[6] low human development, a low GDP and a relatively low combined primary, secondary and tertiary gross education enrolment ratio of 63 per cent[7] indicate that Uganda's scientific and technological development is currently at a low level.

Accordingly, 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.[8]

Comparable observations were made in a 2007 ICTSD report, 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."[9]

The country's current weak level of technological expertise has important implications for the design of its domestic intellectual property laws, as will be explained below.

Poor countries like Uganda depend on the transfer of foreign technologies for their economic and social development.[10] As conceptualized by UNCTAD, "technology transfer involves the transfer of physical goods (e.g. capital goods) and the transfer of tacit knowledge. The latter is becoming more important and involves acquiring new skills and technical and organizational capabilities."[11]

Product innovation may encourage consumption and thus rising incomes, which in turn would lead to differentiated consumer demands and thereby further stimulate product innovation. Process innovation may result in considerable decreases in production costs. In a longer-term perspective, technology transfer not only generates new products and higher productivity, but also provides a source of learning to countries seeking to develop their domestic technological capacities. In a world where everyday life and economic and social progress are increasingly dependent on technology applications, the building of technology expertise is crucial to a country's international competitiveness.[12]

There are essentially two modes – formal and informal – of technology transfer. Technology may be transferred formally, as a commercial operation "that takes place through firm-to-firm

arrangements and involves flows of knowledge, be they embodied in goods (as in the sale of machinery and equipment) or in the form of ideas, technical information and skills (through licensing, franchising or distribution agreements) and movement of experts and skilled labour".[13] Provided a number of other factors are taken into account, formal means of technology transfer may in certain cases be encouraged through appropriate management and use of intellectual property tools, such as through licensing arrangements.

By contrast, informal means of transferring technologies take place outside of formalized commercial and/or legal agreements and include duplicative and creative technology imitation and adaptation, for instance through reverse engineering of existing technology products. Exclusive rights in these products tend to make informal transfers of technology more intricate.[14]

Technology transfer to developing countries and LDCs has long been a pivotal aspiration of the international intellectual property system. The TRIPS Agreement has reaffirmed "transfer and dissemination of technology" as one of the fundamental goals of intellectual property protection (article 7) and obligated developed WTO members to "provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer" to LDC members "in order to enable them to create a sound and viable technological base" (article 66.2).[15]

Some basic observations should be made at the outset.[16] First, the extent to which intellectual property protection exists in a given country is not the only criterion for the question of whether foreign technologies are transferred and effectively absorbed in the receiving country. While intellectual property protection plays an important role for investment decisions in areas involving R&D-intensive, complex and easily imitated technologies, foreign investors attach relatively little weight to intellectual property protection in areas of old, standardized and labour-intensive technologies that require little R&D.[17] In any case, foreign investors will only be attracted to transfer technologies if the host country has created a conducive business environment, involving many other, non-intellectual property-related factors, such as the overall investment climate, including financial incentives and the existence of market demand; the quality of the country's infrastructure; the efficiency of certain administrative approval procedures; and the degree of unethical conduct among authorities.[18]

Second, technology transfer through foreign investors 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 intellectual property system should be tailored to its level of technological development, allowing access to information required to build domestic skills. Thus, in the case of Uganda, capacity-building activities should be an important component of a transfer of technology strategy.

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, information and communication technologies (ICTs), and health, as discussed in section 3 of this chapter). In this vein, the main objective of any future national strategy on technology transfer should be to reach a stage where stakeholders (industry, scientists, but also the general public) are in a position to better absorb knowledge and to use it in their particular environment.

For the general public, this means an improved educational standard through increased access to educational materials (this is the subject of chapter III of this report). For industry

and science stakeholders, this means an enhanced ability to understand foreign technologies and adapt them to local conditions and preferences, or to come up with new uses of existing products (such as in the area of pharmaceuticals). Section 5 of this chapter will, inter alia, explore how some IPRs or alternative mechanisms may be used as tools to stimulate Uganda's capacities in incremental innovation.

2. Institutional set-up and objectives of the government

Issues related to technology transfer are handled by a variety of institutions that are briefly described in this section. One important element of technology transfer is, as suggested above, the creation of domestic technological absorptive capacity. Such capacity may be promoted through specific policies, but also through an appropriately staffed intellectual property office, which could use its technical capacity to extract new technical information from patent applications. Both issues will be discussed in the following section.

The Uganda National Council for Science and Technology (UNCST) is charged with the development and the implementation of policies and strategies for integrating science and technology into the national development policies. It reports to the Ministry of Finance, Planning and Economic Development. The UNCST also provides policy advice to the government as regards science and technology and coordinates and guides national R&D.[19] Finally, the UNCST is mandated "to protect intellectual property through appropriate patent laws and to operate a national patent office".[20]

While UNCST staff would, according to interviews conducted with local stakeholders, have the technical capacity to understand technology issues included in patent applications, they are in practice not involved in the process of examining and granting patents.[21] While any patent applications in Uganda are examined by the African Regional Intellectual Property Organization (ARIPO) under the Harare Protocol, the agency communicating with ARIPO is not the UNCST, but the Uganda Registration Services Bureau (URSB). This is an autonomous statutory body, established under the Uganda Registration Services Bureau Act (Ch 210). The Ministry of Justice and Constitutional Affairs has the power to establish the URSB's general policies.[22] The URSB's objective is to "administer and give effect to the relevant laws and to provide registration services and collect and account for all revenue provided for under those laws"[23]. One of its functions is "to carry out all registrations required under the relevant laws".[24]

Section 3 of Uganda's Industrial Property Bill (2007) and part V of the Uganda Registration Services Bureau Act determine that any registration of industrial property shall be carried out by a registrar who is a staff member of the URSB. A similar provision is included in section 41(1) of the Copyright Act (2006), according to which the URSB Board has the right to recommend a Registrar of Copyright to be appointed by the Minister of Justice. As a consequence of this, the URSB registers patents (after ARIPO examination), trademarks and copyrights.

Interviewed stakeholders expressed the concern that URSB staff do not have the capacity to grasp technological information included in patent applications. This lack of capacity would not only prevent them from effectively examining patent applications, but at the same time from absorbing new technical information and building domestic technological capacities.[25] Stakeholders expressed the view that in order to address this problem, a national intellectual property office would have to be comprised of both lawyers (for the registration process and examination of procedural legal requirements, especially in trademark law) and technical experts (for an examination of the involved technologies, as well as the dissemination of related knowledge after patent expiry). Stakeholders also expressed doubts as to whether the intellectual property office should be located within the Ministry of Finance, Planning and Economic Development, as is currently the case with the UNCST.[26]

In addition to the UNCST and the URSB, there are some other important stakeholders in the area of technology development. The Uganda Industrial Research Institute (UIRI) undertakes applied research and develops and acquires technologies for the strengthening of Uganda's various industrial sectors.[27] As opposed to the UNCST, the UIRI reports to the MTTI. The UIRI is not directly involved in the formulation of technology-related policies.

The Ministry of Information and Communications Technology provides strategic leadership and develops policies and laws in the area of ICT. The ministry has in particular developed the National Information and Communication Technology Policy, as discussed in section 4 of this chapter, below.

Finally, it should be noted that there are other institutions in Uganda dealing with research in specific technology sectors.[28] It would, however, go beyond the scope of this report to cover these institutions.

As of 2009, Uganda has no overall national strategy directed at encouraging the transfer of foreign technologies. The 2009 National Science, Technology and Innovation Policy,[29] the biotechnology policy and the National ICT Policy address issues related to technology transfer, but cannot be considered as being an inter-institutional technology transfer strategy as such. While biotechnology and ICT both have an important economic potential, a specifically dedicated policy is too narrow to address broad technology transfer issues in other sectors of industry. The Science, Technology and Innovation Policy does expressly state as its goal the strengthening of national capabilities "to generate, transfer and apply technologies",[30] and refers to a number of "Strategic Policy Implementation Actions" that provide, inter alia, for the creation of "a system to facilitate the transfer, promotion and development of technologies".[31] However, the Science, Technology and Innovation Policy does not specify what should be the elements of such a system.

The Uganda Millennium Science Initiative (MSI), launched by the UNCST and the UIRI, does not constitute a technology transfer strategy, but a government-sponsored programme for the award of research grants for, inter alia, the promotion of Uganda's scientific and technological base. The MSI does not provide for guidelines and strategies for the transfer of technologies. Rather, it seeks inputs from innovative individuals for transferring technologies in individual cases.

It would seem important for Uganda to agree on an overall strategy of how to promote the transfer of technology. Such a strategy should include elements that are valid in all sectors of industry. In general terms, a transfer of technology strategy should at least include the following elements:

1. The overall goal, which would be the promotion of Uganda's technological capacity for the benefit of society, in particular the capacity to learn technologies, adapt them to local needs and circumstances and disseminate knowledge;

2. A number of specific goals, such as:
   (a) The promotion of technological literacy and skills, including both specific science and general education;
   (b) The promotion of incremental innovation, especially in the forms of adaptations and new uses of existing technologies;
   (c) The promotion of partnerships between domestic and foreign R&D actors;

3. Designing the tools to implement the overall and specific goals, such as:
   (a) Creating the appropriate institutional framework by providing linkages and coordination among technology-relevant government agencies (i.e. the

MTTI/UIRI; the Ministry of Finance, Planning and Economic Development/UNCST, the Uganda Investment Authority (UIA), the Ministry of Health (MoH) and the Ministry of ICT, R&D institutions such as Makerere University and the private sector (i.e. industry and financial institutions engaged in the funding of technology transfer activities);

(b) Designing the legislative framework on intellectual property (patents, utility models and possibly alternative mechanisms, trade secrets, copyright) and other areas (e.g. the UNCST Research Registration and Clearance Policy and Guidelines (2007), the Access to Genetic Resources and Benefit Sharing Regulations (2005) and the Uganda Investment Code Act (1991));

4. Providing for periodic reviews of the above goals and tools.

Such an overall technology transfer strategy would have to be complemented by sectoral policies to facilitate technology transfer, as they already exist, for example, in the areas of ICTs and biotechnology. These policies should take account of the particular needs of a specific sector, which cannot be addressed by an overall strategy. In particular, the involved government agencies and private sector stakeholders should address issues such as:

1. What are the technological needs in different sectors of industry? Where can these technologies be sourced from? Is it practically and economically feasible to import and use/adapt such technologies in the domestic context?[32]

2. Which categories of IPRs may be considered as conducive to the building of technological capacities in a given sector, and which categories of IPRs should be approached with care?

3. What is the role of research institutes and universities in the technology creation and transfer process?

4. What are indicators of success or failure of initiatives aiming at the building of technological capacities? Indicators that could be considered in this context are, for instance:
    - What is the amount/percentage of resources devoted to innovative activities in the public and private sector?
    - Are there increasing linkages between public and private R&D activities?
    - What is the percentage of domestic applicants for patents and utility models? Is this number increasing, compared to past years?
    - To what extent have specific technology promotion projects, such as the MSI by the UNCST and the UIRI, resulted in concrete and useful results?
    - Is there a growing number of R&D collaborations between domestic and foreign actors in selected areas of technology (e.g. agriculture, education, ICT, health)?
    - What is the number of university students enrolled in engineering, biology and chemistry programmes? Is this number growing?

Section 5 of this chapter seeks to provide some guidance on how Uganda's intellectual property legislative framework could be designed in order to contribute to a transfer of technology strategy.

3. Review of some selected technology transfer projects and initiatives

Foreign direct investment (FDI) is considered as one principal channel for formalized technology transfer flows, alongside licensing agreements, joint R&D arrangements, sales and management contracts and informal means of transfer such as imitation.[33] In Uganda,

some of the sectors that have been identified as investment priority areas are, to an important extent, dependent on the successful transfer and absorption of technologies. These sectors include ICTs, health, education and agriculture/agribusiness.[34]

The promotion of foreign investment into these (and other, less technology-relevant) sectors has been considered as an area of high priority for the overall development of the country, as illustrated by a number of Presidential Investors Round Tables.[35] While these round tables have established a number of working groups and issued recommendations in areas that may be considered as preparing a technology transfer-friendly environment (e.g. education, infrastructure and the regulatory environment), they do not refer to the issue of technology transfer as such (and its relationship with investment). According to various interviews conducted with stakeholders, there do not seem to be any broader technology transfer initiatives, due to the lack of an overall transfer of technology policy.[36] ICTSD has found that:

> Notwithstanding various World Bank or multi-donor-funded projects undertaken during the period of economic reconstruction beginning in the mid-1980s, few of these included the transfer of technology or know-how to Uganda. … In relation to article 66.2 of the TRIPS Agreement, Uganda does not appear to be currently benefiting from any specific programmes or initiatives from developed countries in terms of provision of incentives to enterprises and institutions in the home country to promote and encourage technology transfer to Uganda.[37]

Some interviewed stakeholders even expressed the view that technology transfer is not taking place in Uganda at all.[38] There are, however, some sectoral activities undertaken by different stakeholders in an uncoordinated manner, which take place mainly in the identified investment priority areas, as follows.

3.1 The health sector

In February 2009, a joint venture between the Ugandan local pharmaceutical producer Quality Chemicals and the Indian generic manufacturer Cipla launched the production of several anti-retroviral (ARV) drugs and an anti-malaria medicament at the new production site in Luzira/Kampala.[39] According to an agreement between these two companies, each firm holds a 50 per cent share in the joint venture, resulting in an even distribution of future benefits among the companies.[40] While production was limited to 8 hours per day as of November 2009, full production (i.e. 24 hours per day) is envisaged for the future.[41]

The range of products made at the Luzira site includes the ARV DUOVIR-N (a combination of three drugs in one tablet, containing the active pharmaceutical ingredients lamivudine, nevirapine and zidovudine), another fixed dose combination containing lamivudine and stavudine, and also the antimalarial product Lumartem (containing artemisinin and lumefantrin).[42]

As of November 2009, the production site at Luzira was limited to drugs formulation activities. All ingredients required for the production of the above-mentioned drugs, including the active pharmaceutical ingredients (APIs), binders, etc., are currently being imported from Cipla's manufacturing plants in India. Cipla is envisaging the establishment of an on-site R&D centre, pending certain developments under Ugandan domestic intellectual property legislation (see chapter II).

The press has reported that the site is "a near clone of a Cipla facility in India, and uses the latest production and packaging equipment from the United States, Germany, Italy and elsewhere".[43] According to Quality Chemicals senior staff, the Kampala site is fully capable of applying good manufacturing practice (GMP) and good laboratory practice.[44] In November 2009, the joint venture submitted a request for WHO pre-qualification,[45] which would open up

possibilities to participate in international tenders, such as by the WHO and other multilateral organizations engaged in drugs procurement activities.

The agreement on the joint venture between the two firms was brokered by the Government of Uganda, i.e. the UIA, with firm support from the Office of the President. While in practice, this joint venture is a low risk investment for Cipla, it did require considerable investment on the part of the Ugandan Government.

Investment incentives provided to Cipla by the government include free land to build the plant, free set-up of the entire infrastructure, including the factory and its production facilities, roads, electricity, water as well as the payment of remuneration of Cipla's pharmaceutical experts for their training activities with local staff (see below). In addition, the government agreed with Cipla to procure from the new plant in Kampala ARVs worth $30 million per year for seven years.[46] Furthermore, the government promised to let the joint venture benefit from a 10-year tax holiday.[47]

Apart from these economic incentives, Cipla seemed to be attracted by the fact that Uganda intends to make use of a number of patent law flexibilities available under the TRIPS Agreement, which facilitate the production of affordable generic drugs in Uganda. For instance, the 2007 draft of the Industrial Property Law takes advantage of a WTO waiver for LDCs, authorizing the suspension of pharmaceutical product patents until 2016. Under India's new patent law, the possibilities for generic producers such as Cipla to produce generic versions of patented drugs in India may be narrowed in the future. Such production may, however, be continued in LDCs that take advantage of the 2016 waiver. In addition, production costs may be kept at a minimum level, because manufacturers are not required to pay any patent licensing fees. It is also hoped in this context that the East African regional market would, in the future, offer economies of scale. Accordingly, Quality Chemicals staff referred to flexibilities under TRIPS as one reason for low production costs at the Kampala site, and has been quoted as stating that "this plant exists largely thanks to TRIPS".[48] This being said, there are current concerns within Cipla that Ugandan intellectual property legislation is not sufficiently taking advantage of flexibilities available under the TRIPS Agreement, which may affect Cipla's investment decisions in the future (see chapter II).

An essential element of the agreement between the two companies is the training provided by Indian experts to Quality Chemicals personnel for the production of the above-mentioned drugs. Training is provided on the job during the production process as well as in key aspects of organizational activities, quality control and quality assurance protocols. Considering the growing importance of technological know-how for countries' international competitiveness, the transfer of tacit knowledge is becoming an increasingly important element of effective technology transfer, as compared to the provision of physical goods.

3.2 The agribusiness sector

The UIRI is implementing a Business Incubation Project, providing assistance to local agricultural communities in the development of small and medium-sized enterprises for the exportation of their produce.[49] The UIRI's incubation facility provides, inter alia, skills training and business advice to local entrepreneurs to bridge the gap between the innovation and the commercialization of a new product.[50] This means that incubation only covers parts of the product development process, i.e. the prototyping and commercialization of the results of R&D activities.[51] Incubation presupposes the capacity to undertake R&D, which in turn presupposes the successful absorption of technology expertise by local innovators. Thus, there seems to be a need to provide for broader strategies and programmes to promote the transfer and absorption of technology for the benefit of local entrepreneurs. According to the UIRI's website, technology transfer-related activities are also taking place in the areas of electronics manufacturing and laboratory R&D for food, minerals and pharmaceuticals.[52]

However, senior UIRI staff pointed out that due to the lack of an overall technology transfer strategy, there is no comprehensive data on available technologies and no means to assess the success of existing technology transfer initiatives.[53]

Apart from these national initiatives, there is a regional programme that focuses on the improvement of communication between scientists and policymakers in the agribusiness sector. The Swedish-funded East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (Bio-Earn) promotes the development and application of biotechnology in Ethiopia, Kenya, Uganda and the United Republic of Tanzania. Through human capacity-building, infrastructure support and policy and networking support, Bio-Earn has reportedly "strengthened national and institutional abilities to assess, develop and implement effective policies for [bio]technology development and dissemination".[54] In addition, the programme promotes collaborative research among scientists and postgraduate students from four universities in the above-mentioned countries, in order to develop biotechnologies "for use in enhancing agricultural productivity", for example through the creation of drought and disease-resistant as well as virus-free vegetables.[55]

3.3 Technology development grants

In a late 2007 announcement (second round of competitions for grants), the UNCST/UIRI-sponsored MSI project under its third category ("Window C") made available grants, inter alia, to firms and researchers that identify technologies of particular interest to the private sector (Mode 1; up to $50,000) and collaboratively develop concrete innovative products (Mode 2; up to $150,000).[56] Mode 1 in particular seeks to promote technology transfer, as grants under this facility may be used to (1) identify technology-related challenges faced by firms; (2) conduct local, national and international searches for available technologies responding to such challenges; (3) enquire about costs and market potential of transferring, adapting, importing and applying identified technologies; and (4) prepare R&D proposals to develop, adapt or modify the identified technologies in collaboration with other firms, universities or research institutes.[57] While results of this second round of competitions are not yet available at the time of writing this report, a preliminary proposals response analysis of a first round in early 2007 shows a rather uneven distribution of institutions having submitted grant proposals in the areas of research grants and undergraduate science and engineering programme development, with Makerere University alone accounting for 83 out of 163 initial proposals made, competing with 28 other institutions.[58] Most proposals were submitted from institutions belonging to the research areas of health, biomedicine and biological science (52 out of 163); agriculture, food and nutrition (34); environment, ecology and conservation (22); and mathematics, computing and information science (18).[59] A final evaluation of the extent to which submissions under the first round of competitions have been successful is not yet available.[60]

4. Legislation, guidelines and policies related to technology transfer

Relevant laws, regulations and policies in this context are, in particular, the UNCST Research Registration and Clearance Policy and Guidelines (2007), the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations (2005) and the Uganda Investment Code Act (1991). In general, these pieces of legislation seek to provide formalized means of technology transfer on the basis of a commercial agreement. The Industrial Property Bill (of 2009) will be analysed in the following section.

4.1 UNCST Guidelines

The UNCST-administered Research Registration and Clearance Policy and Guidelines (hereinafter "the Guidelines")[61] have the overall objective of documenting research and development activities in all sectors "so as to enable research coordination and oversight,

research priority setting, the protection of intellectual property and use of research results to guide public policy formulation."[62] The specific objectives of the Guidelines do not expressly refer to the promotion of technology transfer, but to the related issue of access to data needed for research in Uganda.[63] The Guidelines in their substantive part contain a number of mandatory basic requirements, but often leave the details up to the parties involved in a research project. For instance, section 9.0 of the Guidelines generally requires foreign researchers planning research activities in Uganda to become affiliated with a local institution appropriate for that type of research. The details of the affiliation may be arranged by agreement between the foreign researcher and the local institution. There are no mandatory rules on the terms of collaboration. The Guidelines in section 9.0 simply state that "local institutions of affiliation should support the researchers and work, as far as it is practicable, towards building long-term collaborative partnerships with the foreign researchers".

This provision leaves much flexibility as to the design of collaborative research agreements. Interaction with foreign researchers could potentially open up opportunities for technology spillovers and knowledge transfers. The researcher could potentially benefit from existing research facilities and other infrastructure, as well as from inputs from local scientists.

4.2 National Environment Regulations

While the UNCST Guidelines apply to any field of technology, the National Environment Regulations (hereinafter "the Regulations") contain a number of provisions specific to the access to genetic resources and the sharing of benefits accruing from the use of genetic resources in Uganda. According to section 6(h) of the Regulations, it is one of the functions of the UNCST as the competent administrating authority "to ensure that technology transfer and information exchange in relation to genetic resources is effected by the persons accessing the genetic resources".

In order to pursue this function, the UNCST may revoke a permit to access genetic resources where the collector has violated any of the provisions of the Regulations.[64] A pertinent provision in this regard is section 20, which lays down the obligation for users of genetic resources to share the benefits arising from such use. According to paragraph 2 of this section, such benefits include, inter alia:

> (e) Transfer of knowledge and technology under favourable terms and, in particular, knowledge that makes use of genetic resources, including biotechnology, or knowledge that is relevant to the conservation and sustainable use of biological diversity;
> …
> (i) Joint ownership of patents and other relevant forms of intellectual property rights.

As opposed to the Guidelines, section 20 of the Regulations lays down a legally enforceable obligation to transfer technology, combined with potential sanctions in case of non-compliance. It does not, however, determine the nature and scope of the knowledge and technology to be shared as a benefit, but leaves this up to individual materials transfer agreements or accessory agreements to be concluded between the user of genetic resources and the lead agency responsible for the management and regulation of access to genetic resources.[65] The lead agency therefore has considerable discretion in the determination of the extent to which the user of genetic resources has to share biotechnologies with domestic stakeholders. Considering the weak negotiating leverage of Ugandan authorities with respect to foreign investors, the effectiveness of such a provision remains to be seen. This situation is comparable to efforts to promote technology transfer under the Investment Code (see section 4.3 below).

The success of these provisions will, inter alia, depend on the extent to which the lead agency actually exercises this discretion. Section 20, in referring to benefits that should be shared, is not limited to transfer of technology issues, but also mentions other potential benefits such as participation by locals in certain scientific research (paragraph (2)(a)); sharing of access fees and royalties (paragraph (2)(b)); and payment of salaries (paragraph (2)(c)). In the absence of an overall technology transfer strategy informing all sectors of government activity, it cannot be excluded that the lead agencies responsible for the negotiation of materials transfer agreements will not be fully aware in all cases of the important technology transfer opportunities offered under the Regulations. Without a nationwide database on needed technologies, lead agencies may also ignore the types of technologies that should be included in materials transfer agreements.

Finally, in order to ensure coherence between environment and patent policy, the Industrial Property Bill should establish a reference to the obligation under the Regulations (section 20) to share the benefits arising from the use of genetic resources. The appropriate place would be section 21(8) of the Industrial Property Bill, which includes a disclosure of origin and prior informed consent requirement for patent applications based on genetic resources or traditional knowledge. This provision could be amended to expressly demand the showing, by the patent applicant, of compliance with section 20 of the Regulations.

4.3 The Investment Code

The Uganda Investment Code Act contains a number of provisions to facilitate technology transfer from foreign investors to Ugandan nationals. Foreign investors wishing to operate a business enterprise in Uganda need to apply for an investment licence with the UIA.[66] The latter shall, when considering such an application, take into account the capacity of the proposed business enterprise to contribute to a number of economic development objectives, such as "the introduction of advanced technology or upgrading of indigenous technology".[67] Theoretically, this provides the UIA with some important leverage in the design of the terms and conditions of the investment licence. Investors that agree to transfer technology are subjected to a number of important conditions potentially generating some significant impact on the technological absorption capacity and economic viability of domestic investment partners. Section 30 of the Investment Code provides that:

> (1) Every agreement for the transfer of foreign technology or expertise shall be subject to the following conditions:
> …
> (d) Any technical assistance shall, where necessary, include technical personnel as well as full instructions and practical explanations expressed in clear and comprehensive English on the operation of any equipment involved;
> (e) The transferee shall acquire the right to continued use of that technology or expertise after the termination of the agreement; and
> (f) The transferor shall, if the transferee so requires, continue to supply spare parts and raw materials for a period of up to five years following the termination of the agreement.
>
> (2) An agreement for the transfer of foreign technology or expertise shall not contain a condition which:
> (a) Restricts the use of other competitive techniques;
> (b) Restricts the manner of sale of products or exports to any country;
> (c) Restricts the source of supply of inputs; or
> (d) Limits the ways in which any patent or other know-how may be used.

However, the success of these provisions depends, inter alia, on the extent to which the UIA actually uses the authorization to consider technology transfer as a key objective under an

investment licence. Again, the creation of an overarching technology transfer strategy instrument, including some guidelines, would likely raise awareness in this respect. In its recommendations, *The Report of the Presidential Investors Round Table Meetings – 2004/6*, prepared by the UIA,[68] does not refer to the promotion of technology transfer through the tools established under the Investment Code. Part of the reason may reside in the fact that Uganda as an LDC has little negotiating leverage vis-à-vis foreign investors, whose intention is often not to collaborate in joint ventures involving the transfer of technology, but to seek modes of investment that are predominantly driven by cost considerations.[69] To address this problem, stakeholders have suggested limiting the validity of an investment licence from the current minimum of five years[70] to two or three years only.[71] However, the government should closely consult with the UIA and other interested stakeholders to ensure that such an amendment does not deter foreign investors. Such consultations would also have to address the issue of determining the appropriate authority to monitor the effectiveness of technology transfer activities by foreign investors.

Under the Investment Code, any investment licence may contain various obligations on the part of the investor, such as "to employ and train citizens of Uganda to the fullest extent possible with a view to the replacement of foreign personnel as soon as may be practicable".[72] Again, while this provision could potentially entail beneficial consequences for domestic technological skills, stakeholders have expressed the view that Uganda as an LDC has too little negotiating power vis-à-vis foreign investors to implement such a provision.[73] For this reason, it would be important to develop appropriate incentives for investors to engage in training of domestic personnel. As the example of the Cipla-Quality Chemicals joint venture illustrates, financial incentives and the provision of the appropriate infrastructure are important elements in this respect.

As in the case of the technology transfer obligation under the National Environment Regulations, the Industrial Property Bill could be used to promote coherence between patent and investment policy. Section 21 of the Industrial Property Bill could be amended to require the patent applicant to show compliance with the technology transfer provisions under section 30 of the Investment Code, to the extent the patent applied for is part of an agreement on the transfer of foreign technology or expertise.

Finally, the UIA seems fully aware of the importance of regional collaboration for the creation of economies of scale to attract investors. In the context of the East African Community (EAC), the UIA is currently contributing to the drafting of an Investment and Industrialization Strategy.[74] Again, these efforts do not seem to be directly targeted at the specific issue of technology transfer.

4.4 The National Information and Communication Technology Policy

Uganda's National Information and Communication Technology Policy of 2003,[75] which is discussed in more detail in the chapter on access to textbooks, also emphasizes the importance of skills transfer to local stakeholders. In order to enable the transfer of relevant technologies from abroad, the policy proposes partnering domestic ICT training institutions with foreign ones, as well as designing incentives to encourage foreign-based Ugandan ICT experts to return to Uganda and make their skills available.[76] Along the same lines, the policy proposes the establishment of an enabling environment for investment into the ICT sector, highlighting the need for paying increased attention to local ownership and participation, as well as the utilization of local facilities.[77] The policy emphasizes the need for substantial investment in the adaptation of ICTs to circumstances prevailing in Uganda.[78]

While all of the above legal and policy documents lay down important rules and guidelines in particular sectors, these provisions cannot replace an overall policy instrument focusing specifically on the promotion of technology transfer, including related guidelines. Due to the

lack of such an overall strategy, there is no mechanism in place to measure the extent to which the above sectoral initiatives and laws have been successful in transferring and absorbing technologies.

5. Analysis of the intellectual property legislative framework relevant to technology transfer

5.1 Introduction

As noted in the introduction to this chapter, effective technology transfer cannot take place without the capacity of domestic firms and researchers to absorb the know-how made available to them. This point is of particular relevance in the LDC context. In addition, if foreign investors are to be motivated to engage in joint ventures generating technology spillovers, they have to be convinced of actual benefits accruing from such arrangements, in terms of inputs of additional expertise, in particular with respect to the adaptation of technologies to domestic conditions (the need for which is also emphasized in Uganda's ICT Policy). This report therefore attaches great importance to the creation of some domestic technological absorption capacity as a prerequisite for subsequent transfers of technologies, in line with existing UNCTAD research.[79]

A country's intellectual property legislative and policy framework can provide important contributions to the creation of an environment conducive to the dissemination of technology-related knowledge and the transfer of technologies. Intellectual property laws and policies can generate impact on two different levels of knowledge: more generally, on access to learning materials – which is the subject of the specific access to textbooks chapter in this report – and more specifically on access to technology information incorporated in industrial products and scientific research activities. The present analysis will focus on the latter.

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 relevant information needed for technological learning, as well as incremental and follow-on innovation. Countries like Uganda, at an early stage of technological development, 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.[80] 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 knowledge building and technology absorption.[81] At early stages of development, exclusive rights in technology information, which in Uganda are mostly held by foreigners,[82] render the use of informal means of technology transfer more difficult or even entirely impossible, thus complicating the creation of domestic technological expertise.[83] This may be seen as one of the reasons for the extension, by the WTO Council for TRIPS, of particular LDC transition periods, prior to which LDCs such as Uganda do not have to comply with most of the TRIPS Agreement minimum standards of intellectual property protection.[84] Once a country reaches higher levels of development, it may still opt for an increase in intellectual property protection, provided an appropriate balance between rights holders and competitors is maintained.[85]

IPRs encourage technology transfer through formal means, such as licensing agreements and joint venture arrangements. In the absence of a certain level of technological expertise in the receiving country, however, there is no basis for actual cooperation between the foreign investor and the local firm. The potential chilling effect of expansive exclusive rights on foreign firms' decisions to invest in a country has also been observed in a 2003 study of the

Organization for Economic Cooperation and Development (OECD) on the impact of IPR protection on FDI, finding that:

> The results do not imply that stronger patent protection (or correlated IPRs) will always raise FDI and trade. There may come a point where these types of IPRs are too strong – in the sense that they grant producers of intellectual products excessive market power – in which case IPRs may negatively influence FDI and trade. Thus, the empirical finding [that there is a positive correlation between IPR protection and the promotion of FDI] is conditional on intellectual property systems not reaching excessive levels of strength.[86]

For developing countries and especially LDCs 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 and to promote what may be considered a realistic achievement in terms of technological development, i.e. the capacity to engage in incremental innovation. 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.

It should be acknowledged, in this context, that an intellectual property system that promotes access by domestic innovators to foreign technologies at the same time facilitates access by foreign firms to domestic technology. Due to the national treatment principle of the TRIPS Agreement, which applies to LDCs even during the transition periods, foreigners may claim access to public domain information to the same extent as Ugandans. In comparison, the creation of innovation from a broad public domain and under flexible patent laws will probably generate higher costs for Ugandans than for highly skilled OECD-based competitors.

For this reason, we think that small-scale innovators, who rely on information available in the public domain, should be granted some form of protection to prevent competitors from the wholesale copying of their inventions. While small-scale inventions should not benefit from patent protection (in order to maintain high standards of patentability and a robust public domain), the role of second tier categories of IPRs such as utility models or trade secrets may be considered, as these generate less impact on the public domain, while nevertheless providing some protection (and thus) incentives for small innovators.

In the present section, we will analyse to what extent Uganda's Industrial Property Bill is in line with the objective of promoting the transfer of technology, and incremental innovation in particular. Provisions with particular public health implications are discussed in chapter II of this report.

5.2 **Patent eligibility criteria** (Sections 10–12, Industrial Property Bill)

Sections 10(2) and (3) lay down a strict novelty standard, providing that any written or oral prior art publicly available (including other applications for patents or utility models) in any country of the world shall destroy the novelty of an invention claimed in Uganda. By restricting the possibilities to claim existing inventions as new, this section contributes to the safeguarding of a public domain needed for domestic researchers' freedom to operate.

This being said, most patent applications in Uganda are channelled through ARIPO, which carries out the substantive examination for all patent applications, even those that are directly filed at the national intellectual property office and then transmitted to ARIPO.[87] According to section 3(9) of the Harare Protocol, only such prior art that has been disclosed

in written form or by use or exhibition shall be considered as destroying novelty. As opposed to section 10(2) of the bill, there is no reference to oral disclosure. In case the core elements of a pharmaceutical invention are disclosed in an oral presentation by a third party (i.e. not the patent applicant), for instance at a university, this would arguably not be considered as prior "use" or "exhibition" of the invention under the Harare Protocol. The stricter standard under section 10(2) of the Industrial Property Bill would in practical terms not be considered, unless the URSB had a means to find out about the oral presentation and communicated this to ARIPO, referring to the stricter novelty standard under Ugandan law.[88] This would have to be done within only six months from receiving a notification from ARIPO regarding the results of the substantive patent examination.[89] While these options seem to raise practical problems, it is at least questionable whether the alternative, i.e. an amendment to the Harare Protocol, inserting a reference to oral prior art, would be politically feasible at the present time.

The above problem arises in particular where the applicant files only a national (i.e. Ugandan) or regional (i.e. ARIPO) application. In case of an international application following the procedures under the Patent Cooperation Treaty (PCT), the major patent offices of the world, designated by the PCT Assembly, carry out the prior art search ("international search") and establish a non-binding, preliminary written opinion on the question of whether "the claimed invention is or seems to be patentable or unpatentable according to any national law" ("International Preliminary Examination Report", article 35(2), PCT).[90] Such an examination would have to take account of the novelty standard under the Ugandan Industrial Property Bill. This being said, the general challenge confronting patent examiners, i.e. work overload, also applies in the case of PCT examiners and might affect their possibilities to conduct exhaustive prior art searches and patentability examinations. In addition, PCT examiners may not be familiar with certain interpretations of national patentability criteria that are not obvious from the sole language of the patent law, especially if the law is new. The latter point applies specifically to the inventive step and industrial application requirements, as explained in the following paragraphs.

The inventive step standard under section 11 is comparable to the one used in many countries. In order to preserve in the public domain technological developments that are predictable from existing prior art, the provision 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 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). This is the approach recently mandated under United States patent law by the United States Supreme Court, thereby considerably raising the bar of patentability.[91]

Finally, the industrial application standard in section 12 corresponds to the standard of many other countries. In order to maintain researchers' freedom to operate, this provision 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 practice by the European Patent Office of denying patents on research tools[92] that are claimed for an undefined variety of different uses.[93]

In case the above interpretations of the inventive step and industrial application standard meet the approval of Ugandan stakeholders, it seems advisable to include them, in express form, in national patent examination guidelines or regulations, or even directly in sections 11 and 12 of the Industrial Property Bill. This would take account of the fact that for PCT applications, the International Preliminary Examination Report is carried out by foreign PCT examiners, who have to rely on written documentation. The sole language used in the current sections 11 and 12 on inventive step and industrial application does not reveal how these requirements should be applied to a concrete case.

5.3 Disclosure of patented invention (Section 39, Industrial Property Bill)

By requiring the inventor to disclose "at least one mode for carrying out the invention", section 39(a) does not take full advantage of the flexibility provided under article 29.1 of the TRIPS Agreement, which authorizes members to require patent applicants to even disclose the best mode for carrying out the invention. This is an important contribution to helping local innovators and researchers fully understand the technology claimed in the patent. 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 to potential competitors of the patentee. A best mode requirement would thus be an important step toward the creation of a pro-competitive environment for technology development and follow-on innovation. It would also respond to Uganda's 2007 Communication to the TRIPS Council of Priority Needs for Technical and Financial Cooperation, where the government emphasizes the need for the development of a patent information service to support innovation and technology transfer.[94] Clearly drafted patent applications could play an important role in this respect. Furthermore, a best mode requirement would also be in line with a 2004 study by the Uganda Law Reform Commission (ULRC), which emphasized the need for the inventor to "effectively disclose how to make and use the invention to the public, which facilitates further technological advances".[95] Finally, it would follow a recommendation made by UNCTAD in a 2008 study on the patent laws of the EAC partner States.[96]

5.4 Experimental use exception (Section 44(a), Industrial Property Bill)

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. Researchers involved in basic 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. An experimental use exemption carves out a "safe harbour" for research activities that might otherwise be blocked by patents.

Another question arises concerning the extent to which researchers in commercial enterprises are authorized to conduct applied research on or with patented inventions for the purpose of developing commercial products based on the protected subject matter, such as improvements or adaptations of existing products or processes, or for discovering ways to "invent around" the patented invention (commercial research). The TRIPS Agreement itself is silent on this question of commercial research and no WTO panel has so far provided any authoritative interpretation of article 30 of the TRIPS Agreement with respect to the question of whether and to what extent it allows commercial research.

Section 44(a) of the Industrial Property Bill exempts from patent infringement claims uses of a patented invention without the authorization of the patent holder "to carry out any acts related to experimental use on the patented invention, whether for scientific or commercial purposes". This is much broader in scope than comparable provisions in many countries, even in the East African region,[97] and in an earlier draft of the Ugandan Industrial Bill.[98]

As to the scope of this exception, the reference to "commercial purposes" should not be interpreted as allowing for activities by competitors whose main purpose is to commercialize the patented invention without the patent holder's authorization. The reference to "acts related to experimental use" makes clear that the overall objective of any activity falling under this provision must be the generation of new knowledge on the protected substance, as opposed to the mere promotion of competitors' commercial activities. New knowledge in this sense should be knowledge that was not contained in the original patent claims or their

equivalents, and may take the form of either new uses of the patented existing substance, or of new knowledge enabling the manufacture of a new product with potentially superior qualities. In order to prevent misunderstandings, section 44(a) of the Industrial Property Bill should be amended to this effect, referring expressly to the overall purpose of the provision as being the generation of new knowledge on the patented product.[99] This would follow the template in article 9(b) of the new Swiss Patent Act,[100] which has been interpreted as allowing experimental use of patented inventions for both non-commercial and commercial purposes, provided that the overall purpose of the activities at issue is the generation of new knowledge on the patented invention.[101]

Further guidance in this context may be found in a 2009 decision by the United Kingdom's High Court regarding the scope of the United Kingdom's experimental use exception. The High Court expressed the view that a commercial purpose behind a competitor's use of patented substances does not automatically rule out the possibility of invoking the experimental use exception. Most pharmaceutical research is driven by commercial considerations. However, the purpose of the experimental use defence/exception is not to promote competitors' commercial activities, but to enable the generation of new knowledge on the protected substance. Thus, the defendant in a patent infringement suit needs to show that the immediate purpose of his activities was not to generate revenue, but to gain new knowledge on the patented product (e.g. to enable future modifications of a drug). Where the defendant's activities have mixed purposes, the generation of new knowledge needs to be the preponderant purpose, while the generation of revenue may constitute a secondary purpose.[102]

The language used in section 44(a) ("experimental use **on** the patented invention", emphasis added) seems to indicate that the exemption does not cover activities that experiment "with" the patented substance, i.e. use it as a research tool to develop new products that are independent of the originally patented product. It is essential, for the promotion of technological progress, to make research tools freely available to scientists. This may be done either by exempting their use from patent infringement claims, or by providing researchers with a right to claim from the patentee a non-exclusive licence for the use of the research tool. The United Republic of Tanzania seems to have adopted the former approach in its Industrial Property Rights Bill (version as of March 2008),[103] while the new Swiss Patent Act provides for a licence of right in the area of patented biotechnological research tools.[104]

The Swiss approach seems to strike an appropriate balance between the need to provide incentives for the development of research tools and the need to make these tools available to the research community. The justification for treating experimental uses "on" the invention differently from experimental uses "with" the invention lies in the fact that experiments "on" the invention do not affect the normal exploitation of the patent by the right holder, while experiments "with" the invention may be the only purpose of a patented research tool. In that case, expanding the experimental use exemption to research tools would render impossible the normal exploitation of the patent.

Along the above lines, a robust experimental use exemption is also needed in case Ugandan universities and research institutes go ahead with their plans to apply for patents on the results of publicly funded research, as is the case with Makerere University.[105] As illustrated by experiences in the United States with respect to university patenting under the Bayh-Dole Act,[106] restrictive licensing of upstream inventions by universities may cause serious bottlenecks in the transfer to the industry of know-how needed for the marketing of new technologies.[107] Such blocking effects could be mitigated by invoking an experimental use exemption that enables industry to use the results of basic research to develop new or follow-on technologies.[108]

5.5 Prohibited terms in a licence contract (Section 55, Industrial Property Bill)

This provision addresses restrictions in patent licences that unduly restrict the licensee's possibilities to benefit from the licensing agreement in terms of technological learning, technology absorption and transfer, and overall economic viability. Article 55(1) states that: "The registrar may refuse to register a licence contract if the registrar is of the opinion that any clause in the licence contract imposes unjustified restrictions on the licensee with the consequence that the contract, taken as a whole, is harmful to the economic interests of Uganda."

The main objective of this provision is to promote technology spillovers from (mostly foreign) patent holders to local licensees. In this sense, this provision may be seen as complementary to article 30 of the Investment Code on conditions in technology transfer agreements between a foreign investor and a domestic partner (see discussion above).

The promotion of technology transfer and dissemination is one of the main objectives of intellectual property protection, according to article 7 of the TRIPS Agreement. Article 8.1 of the TRIPS Agreement authorizes members to formulate their laws in a way that is conducive of promoting "the public interest in sectors of vital importance to their socio-economic and technological development". Article 8.2 of the TRIPS Agreement authorizes members to adopt appropriate measures to, inter alia, prevent practices by intellectual property holders that adversely affect the international transfer of technology. Section 55 of the Industrial Property Bill may be based on these authorizations. It would be useful, in this respect, to expressly refer to the protection of intellectual property as a means to promote technology transfer in an overall intellectual property policy document (which remains to be established).

Most of the practices listed under section 55 have parallel provisions in article 30 of the Investment Code, which is of particular importance in the present context. It states that:

> (1) Every agreement for the transfer of foreign technology or expertise shall be subject to the following conditions:
> …
> (e) The transferee shall acquire the right to continued use of that technology or expertise after the termination of the agreement; and
> …
>
> (2) An agreement for the transfer of foreign technology or expertise shall not contain a condition which:
> …
> (d) Limits the ways in which any patent or other know-how may be used.

Subsection (d) of this provision should be understood as not limiting the use by the licensee of intellectual property-protected technology that was part of the transfer agreement. A similar understanding is warranted in the case of section 55(2)(s) of the Industrial Property Bill. It considers an unjustified restriction in a licensing agreement any terms that:

> … impose confidentiality after the expiry of the licence agreement or … impose unreasonably long periods for secrecy following the commissioning of manufacturing facilities using the licensed technology, **or … impose measures which limit technological learning and mastery, except those which relate to industrial property rights**. (emphasis added)

The same observation applies in the context of section 55(2)(x), which considers as restrictive any terms that "restrict the licensee from taking measures that will enhance

Ugandan technological capacity **and which are not prejudicial to the licensor's industrial property rights**". (emphasis added)

It is not clear what is meant by "prejudicial", and which IPRs are decisive in this context. The licensee should have the right to use the licensed intellectual property to build his own expertise, in line with article 7 of the TRIPS Agreement and the above provisions under the Investment Code. Paragraphs (s) and (x) of section 55 of the Industrial Property Bill should be understood as being limited in their scope to those IPRs that are not encompassed in the licensing agreement. A licensee cannot expect to have access to technologies and expertise that is not included in a licensing agreement. As to those IPRs that are actually licensed, the law should not encourage licensors to further limit licensees' rights in a way not consonant with the objective of intellectual property protection under the TRIPS Agreement and the technology transfer provisions under the Investment Code.

Finally, it is important to note that section 55 does not seem to address a number of important anti-competitive practices, as enumerated under article 40.2 of the TRIPS Agreement, i.e. exclusive grantback conditions and conditions preventing challenges to validity. Exclusive grantback conditions may be defined as those contractual practices "requiring the acquiring party to transfer or grant back to the supplying party, or to any other enterprise designated by the supplying party, improvements arising from the acquired technology, on an exclusive basis, without offsetting consideration or reciprocal obligations from the supplying party, or when the practice will constitute an abuse of a dominant market position of the supplying party".[109]

Conditions preventing challenges to validity have been defined as conditions "requiring the acquiring party to refrain from challenging the validity of patents and other types of protection for inventions involved in the transfer or the validity of other such grants claimed or obtained by the supplying party, recognizing that any issues concerning the mutual rights and obligations of the parties following such a challenge will be determined by the appropriate applicable law and the terms of the agreement to the extent consistent with that law".[110]

Anti-competitive agreements are addressed under part VI of the Ugandan Draft Competition Act (version of 2004). However, neither of the above-mentioned anti-competitive practices is mentioned under those provisions. In addition, the Draft Competition Act, while defining abuse of dominance (part VII), does not specifically refer to abuse of intellectual property. As this notion is relevant under both intellectual property and competition law, it would seem appropriate to include a definition of intellectual property abuse under both the Ugandan Draft Competition Act and the Industrial Property Bill, in a coherent manner.

For this purpose, the TRIPS Agreement is silent on the notion of "abuse", leaving its definition up to each member. National laws in various WTO members differ on what they consider to be abusive practice. The meaning of "abuse" has been the source of considerable controversy. While a few developed countries, notably the United States, limit the concept to anti-competitive practices bordering on antitrust violations,[111] the TRIPS Agreement does not oblige members to limit the scope of intellectual property abuse to violations of competition law. Members may consider abusive any use of an IPR that defeats its core purpose of promoting innovation and technology dissemination, even where the IPR holder in question is not in a position of market dominance.[112]

For the purpose of determining the extent of "abuse" under national legislation, the United Nations Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices provides some guidance. According to the set:

> Whether acts or behaviour are abusive or not should be examined in terms of their purpose and effects in the actual situation, in particular with reference to whether they

limit access to markets or otherwise unduly restrain competition, having or being likely to have adverse effects on international trade, particularly that of developing countries, and on the economic development of these countries and whether they are:

> (a) Appropriate in the light of the organizational, managerial and legal relationship among the enterprises concerned, such as the context of relations within an economic entity and not having restrictive effects outside the related enterprises;
> (b) Appropriate in light of special conditions or economic circumstances in the relevant market such as exceptional conditions of supply and demand or the size of the market;
> (c) Of types which are usually treated as acceptable under pertinent national or regional laws and regulations for the control of restrictive business practices.[113]

5.6 University intellectual property policies

In one of its publications, the Bio-Earn Programme considers intellectual property management "an increasingly important part of research collaboration, technology transfer and commercialization of research".[114]The development of institutional intellectual property management policies or structures within East African research institutions is considered to "encourage innovation, facilitate international collaboration, assure scientists of a reward system and attract private sector investment in science-based enterprises".[115] The objective of such intellectual property management policies would be to enable the patenting by universities and research institutions of the results of publicly funded research, along the lines of the 1980 Bayh-Dole Act in the United States. As stated by So and others in a recent article:

> Bayh-Dole encouraged American universities to acquire patents on inventions resulting from government-funded research and to issue exclusive licences to private firms, on the assumption that exclusive licensing creates incentives to commercialize these inventions. A broader hope of [Bayh-Dole], and the initiatives emulating it, was that patenting and licensing of public sector research would spur science-based economic growth as well as national competitiveness. And while it was not an explicit goal of [Bayh-Dole], some of the emulation initiatives also aim to generate revenues for public sector research institutions.[116]

Accordingly, Makerere University has had an intellectual property policy in place since 2006, which seeks to protect university inventions and ensure returns from their commercialization.[117] There are no provisions in the Industrial Property Bill that specifically address the patenting of inventions resulting from publicly funded research. Provided these inventions do not fall under any of the exclusions from patentability in section 8(3) of the Industrial Property Bill and meet the requirements of novelty, inventive step and industrial application, the Industrial Property Bill does not stand in the way of university patenting.

In this context, it is important to refer to serious concerns, expressed in the literature, regarding potential negative effects in the United States of the Bayh-Dole Act on research activities and technology transfer and innovation.[118] In brief, some of the most important lessons drawn after 28 years of experience with the Bayh-Dole Act are the following:[119]

- The role of university patents in the promotion of technology innovation has been largely overstated; other features unique in the United States are of much more importance in this connection, such as generous public funding of university R&D;

- According to empirical research, a significant share of the few university patents and licences that resulted in commercial products could have been effectively transferred either in the public domain or under non-exclusive licences;
- The returns earned by universities from the licensing of inventions are much lower than usually expected, accounting for not even 5 per cent of total academic research income (i.e. non-patent-related public and industry funding). This may partly be explained by the high costs of licensing patents, which do not only include legal fees, but also the operating and salary costs for technology transfer offices.[120] According to recent research, "net returns from patenting and licensing by US universities are, on average, quite modest", and "universities should form a more realistic perspective of the possible economic returns from patenting and licensing activities";[121]
- The patenting of upstream research results may lead to patent thickets and thus complicate the transfer of technology to industry;
- Non-exclusive licences granted by universities to industry do not seem to have had a negative impact on transferring and commercializing technologies;
- There is a danger that universities apply a "one size fits all" model to the patenting of research, even though different areas of technology respond differently to patent protection (e.g. the pharmaceutical sector and the ICT sector).

Considering the above, it seems at least doubtful whether a Bayh-Dole approach to university research and technology transfer is appropriate for Uganda. Researchers in developed countries increasingly recognize the need for collaborative and open research, which is not promoted by exclusive rights, but through open source innovation, scientific commons or at least the collective management of intellectual property (e.g. open, non-discriminatory patent pools). Aggressive university patenting may end up inhibiting the very collaboration with other researchers and the private sector that some Ugandan stakeholders have been emphasizing. While it is understandable that universities and research institutions seek additional sources of income, it is at least questionable whether Ugandan firms are willing or even capable to pay licensing fees for using technologies generated by university research. In the end, it could be affluent foreign firms that bring these technologies to (foreign) markets, thus the process of technology development, transfer and innovation would bypass Ugandan domestic firms.

Against this background, the government may want to consider putting in place a number of safeguards, some of which have been suggested in the literature.[122] A first safeguard in this respect would be to maintain Uganda's priority for a full implementation of the TRIPS Agreement flexibilities. For instance, as analysed above, the patent eligibility requirements under sections 10–12 of the Industrial Property Bill were drafted with a view to maintaining a broad public domain. Enabling the patenting of university research, possibly academic research tools, should not lead to the patenting of research tools for which no particular use has been specified in a patent application. Such a wide application of the industrial application requirement could have a blocking effect on follow-on research.

Second, universities should not license their patents, in particular research tools, on an exclusive basis. Licensing an invention to many firms at the same time will ensure technology improvement through inter-firm competition much more than under monopoly conditions.

Third, institutions that patent publicly funded research results should be publicly accountable for their activities. They should be required to make public all information necessary to assess whether they are actually serving the public interest, such as the number of patents and licenses obtained, funds spent, revenues from licensing and terms of the licence. In this vein, the government could make the availability of research funding (be it from its own or from foreign sources, such as state agencies or private donors) dependent on the extent to which research institutions are prepared to license patented technologies into a common

patent pool, which should be open for new entrants and make available all patented technology for all interested parties on certain, predetermined terms (including modest licensing fees, affordable to local stakeholders). Third parties interested in using a publicly funded university invention could be provided a licence of right to use the invention, in exchange for remuneration payable to the university.

Fourth, the government should preserve its own right to override a licence that does not succeed in promoting technology transfer and innovation ("march-in rights").

Finally, the government should also have at its disposal the discretion to issue a government use licence for the patented invention, as authorized under the TRIPS Agreement.

5.7 Utility model protection

As outlined in the introduction to this section, utility models may be an appropriate way of encouraging incremental innovation. 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.

Section 68(1) of the Industrial Property Bill makes most of the provisions regarding patents applicable to utility models, including the exclusive rights provided under section 38. These rights shall last for 10 years counted from the date the utility model is granted (section 69(3)). Eligible inventions have to be new and industrially applicable in the patent sense, but do not need to meet the inventive step requirement (section 69(1) and (2)). While the worldwide novelty standard seems appropriate in the patent context, it is questionable to what extent domestic small-scale inventors, who are expected to benefit most from utility model protection, will be capable of meeting this rather strict standard. It would seem that local innovators are better served by introducing, through legislative amendment, a domestic novelty standard specifically in the context of utility model protection.

The term of protection for utility models in Uganda (i.e. 10 years from the granting date) seems quite long as compared to parallel provisions in other countries: Australia provides for a maximum term of eight years[123] and utility model protection in Germany normally lasts for a term of three years, renewable in several instances up to a total of 10 years.[124] As opposed to the situation in Uganda, Australia and Germany make protection dependent on the existence of an – albeit lower – inventive (or "innovative") step. On the other hand, if our recommendations on the tightening of patentability standards are implemented, local innovators will often be excluded from patent protection, due to the rather low level of their inventive activities. This may be justified against the assumption that a robust public domain is important to promote access by technology learners to needed information. This being said, local innovators will still need some incentives to engage in potentially costly and time-consuming R&D. In order to accommodate such a need, a 10-year period of utility model exclusivity may constitute an appropriate means. Alternatively, a non-exclusive "use and pay" regime is suggested in the next section to address possible concerns about blocking effects that utility model systems may have on the public domain. It will be a matter of national preference to decide whether to favour exclusive or non-exclusive incentive schemes.

5.8 The promotion of incremental innovation through "use and pay" regimes

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. Supporters of a robust public domain may question to what extent such exclusivity, especially a relatively long term such

as 10 years, may be justified in the case of inventions that do not even meet an inventive step threshold.

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. This approach addresses concerns about blocking effects of exclusive rights in substances needed by competitors, but at the same time provides some incentives for small-scale innovators to invest in incremental innovation. In the literature, such a system has been suggested to stimulate incremental innovation in general[125] as well as in new applications of traditional knowledge in various contexts.[126]

In practice, the International Treaty on Plant Genetic Resources for Food and Agriculture establishes a use and pay regime for plant breeders who breed new varieties off of exemplars deposited in a repository managed by the Consultative Group on International Agricultural Research. Similarly, the United States Federal Insecticide, Fungicide and Rodenticide Act establishes a use and pay system in the area of agricultural chemical test data, which is, however, preceded by a 10-year term of exclusivity in these data.

A use and pay/compensatory liability regime, as suggested in the literature basically confers three separate rights on the incremental innovator:[127]

1. The first right is the right to prevent second comers, for a certain period of time, from wholesale imitations of the right owner's product. In the case of traditional knowledge products, the term of protection could be longer than for other small-scale innovation, taking account of the slow accretion of traditional knowledge over time. A term of protection of 20 years has been suggested in this context.[128] In areas of more systematic, commercially driven technological innovation, the term of protection could be shorter, also taking account of divergent lengths of product life cycles. There would be no need to protect short-lived innovations from wholesale copying for a period of more than a few years;

2. Under the second right conferred, the incremental innovator may claim reasonable compensation from any party that uses the protected innovation for value-adding improvements, for a specified period of time. This right, which could last for up to 20 years, 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. Under the subsequent, longer period of compensation, the original innovator would be prevented from blocking access by competitors to his innovation, unless wholesale duplication is sought. This differs from a utility model regime, under which competitors would generally be excluded from the use of the protected substance for follow-on improvements, in any case where they follow commercial purposes. As to the amount of compensation payable to the incremental innovator, Reichman has suggested royalty rates between 3 and 9 per cent of the sales revenue of the improved product.[129] The amount of payable royalties would, inter alia, depend on the amount of resources needed by the second comer to develop the improved technology or application. Disputes over the amount of royalties to be paid to the incremental innovator should be settled through mediation or arbitration. Importantly, the mediation or arbitration procedures would not entitle the right holder to ask for an injunction; thus his technology could be used for follow-on improvements, while all royalties would be payable after the final mediation or arbitration award is rendered;

3. Finally, the third right conferred under a use and pay regime 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 (i.e. to claim reasonable compensation for improvement uses of the original technology), but this would be up to policymakers to decide.

In most cases it will not make sense to implement a utility model regime and a use and pay regime in coexistence. The purpose of the use and pay regime is to avoid the kind of blocking effects generated by exclusive utility models. Taking account of the importance of an accessible public domain for incremental innovation, a use and pay regime seems to be at least as appropriate for technological learning in Uganda as an exclusive rights-based utility model regime. On the other hand, it has to be acknowledged that the introduction in Uganda of an untested use and pay regime will generate some learning costs. The incremental innovator must have the possibility to have his innovation registered. This could possibly be done with the authority responsible for the registration of utility models (i.e. the URSB) and would arguably avoid any additional costs. What could prove more difficult is to determine the royalty to be paid to the innovator. Experienced mediators or arbitrators would be needed, and a court would have to be in place to supervise the resulting awards. In addition, a number of technical details would have to be agreed upon before a use and pay system could be useful in the Ugandan context, for example, whether it should benefit local innovators only, or also apply to foreigners, and whether such system would rely on a "first to file" or "first to invent" principle.

Taking the above considerations into account, the government may wish to consider testing the use and pay approach in a limited area, while maintaining the utility model regime in place until the first experiences in the operation of compensatory liability regimes have been collected. The TRIPS Agreement does not impose any restrictions in this regard. The government could limit the use and pay approach to the promotion of new applications of traditional knowledge, before considering an extension to areas of targeted, commercially driven R&D. Under such a regime, communities willing to make their traditional knowledge publicly available would be entitled to prevent others from the slavish reproduction of their know-how, for a period to be determined in an agreement between the government and the provider communities. In addition, the latter would be eligible to receive compensation from users for improvement applications of their knowledge, for a period of time that could last much longer than under the current Ugandan utility model regime (e.g. 20 years from the date of making the traditional knowledge available).

5.9 Trade secrets protection

In June 2009, the Ugandan Trade Secrets Protection Act 2009 entered into force.[130] Prior to this new legislation, there was no law protecting trade secrets in Uganda. Eligible for protection is information that (1) is not generally known (i.e. secret) among persons that usually deal with comparable information; (2) has commercial value because it is secret; and (3) has been subject to reasonable steps, by the holder of the information, to keep it secret.[131]

While a patent on a product prevents the unauthorized reverse engineering of that product and even its independent development, trade secrets protection is based on the concept of "unfair competition" under article 10*bis* of the Paris Convention,[132] which does not rule out the discovery and appropriation of someone else's undisclosed information through honest commercial means, such as independent development and reverse engineering.[133] While trade secrets thereby provide a possibility for competitors to access technology-relevant information, they also provide protection to (often foreign) technology developers and entrepreneurs. Such protection may give foreign investors some confidence to transfer certain technologies to domestic counterparts (provided the latter are capable of absorbing the incoming know-how). This seems especially important against the background of article 8(3)(b) of the Industrial Property Bill, which excludes methods for doing business from patent

protection. It appears legitimate to seek non-exclusive forms of protection for business plans, as the denial of any protection would likely have a deterring effect on many foreign investors, including generic producers of pharmaceuticals. In addition, trade secrets protection does not depend on any formalities, such as registration, but comes into effect as soon as certain information meets the eligibility requirements, as discussed above.

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. This is similar to the situation under copyright law, where independent creation is also a defence to copyright infringement allegations, but differs from patent law, where the claimant only needs to show the unauthorized use of the protected substance by the defendant.

The Trade Secrets Protection Bill is silent on the allocation of the burden of proof. In other jurisdictions, there seems to be a lack of consensus in this regard. Under United States law, for instance, there is no uniform approach among state jurisdictions.[134] While it is established practice that use of the protected information by the defendant (to be shown by the plaintiff) may constitute a prima facie case of trade secrets misappropriation, there is some controversy, at least among United States courts, regarding the question of how to allocate the burden of proof after the defendant has countered the misappropriation claim by asserting independent development.[135] This has an important impact on the effectiveness of trade secrets protection.

- According to one approach, the defendant, upon raising the defence of independent development, has to substantiate this defence by showing that he has substantial capacity to independently develop matter claimed to be secret by the plaintiff. Upon such showing, however, it is up to the plaintiff to disprove the defence by showing that in the particular case, the defendant, despite his alleged capacity, did not arrive at the protected information through independent means. Thus, the plaintiff has to prove a negative. If he fails to do so, the defence advanced by the defendant will be upheld and reverse the prima facie presumption of misappropriation that was established by the defendant's use of the protected information;[136]

- The problem with the above approach is that it imposes the burden of proving a negative on the plaintiff despite the fact that the latter in general has no access to the relevant information on how the defendant arrived at discovering the protected know-how. It would seem more appropriate to burden the party that has better access to such information.[137] Otherwise, the use of trade secrets to protect information is seriously limited. In this vein, it seems reasonable to expect the defendant to show that he had the capacity to arrive at the use of the protected information through his own, independent means. Under this approach, the defendant, upon asserting independent development, would not only have to show his general capacity to do so, but would also have to persuade the court that in the particular case, he effectively arrived at the protected information through independent means. If he failed to do so, the prima facie presumption of misappropriation as established through the use by the defendant of the protected information would remain valid.

Considering Uganda's important need to build domestic technological capacities through informal means of technology transfer, and considering at the same time the country's dependence on foreign technology inputs through investment and other means, effective trade secrets protection combined with elevated criteria for patentability could possibly strike an appropriate balance between the interest of foreign investors and local competitors. In order to ensure effective protection, the government may want to consider adopting, either in the recently enacted Trade Secrets Protection Bill or in separate administrative regulations, a general rule on the allocation of the burden of proof, along the lines described above.

6. Summing up: Main recommendations

6.1 Policy level

The above analysis has shown the importance of a national (i.e. inter-institutional) strategy on technology transfer. The promotion of technology transfer is a policy objective that cuts across various sectors of a country's domestic policy, ranging from economic and legal to infrastructural and governance issues. Actors in various agencies must be aware of the importance of technology transfer for their activities, as shown by the example of the Investment Code and the potential, for the UIA, to exert an impact on the design of investment licences under technology transfer agreements (see above). For this reason, it seems essential for any country seeking to attract technologies to adopt an explicit strategy directed at encouraging the transfer of foreign technologies.

Recommendation no. 1: Adapt a transfer of technology strategy
The overall objective of a strategy on technology transfer would be to promote overall, coherent principles and move away from uncoordinated and merely sectoral initiatives. Such an overall technology transfer strategy would have to be complemented by sectoral policies to facilitate technology transfer, as they already exist for example in the areas of ICTs and biotechnology. These policies should take account of the particular needs of a specific sector, which cannot be addressed by an overall 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 for success of technological learning and dissemination, as outlined in section 2 of this chapter.

6.2 Institutional level

Technology transfer is a cross-cutting issue that should be promoted by many different institutions and ministries (trade and industry, health, agriculture, education, etc.). However, it is important for these different actors to pursue their specific technology transfer policy initiatives in a coordinated and mutually supportive manner. An overall technology transfer strategy as suggested above is indispensable in this regard.

Recommendation no. 2: Ensure that the institutional set-up of the intellectual property office is conducive to the transfer of technology strategy and the general innovation policy vision of the country
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. 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 relevant technical information from patent applications, in addition to legal and administrative staff for the intellectual property registration procedures. This could also promote exchanges between the intellectual property office and domestic research institutions, which could increasingly benefit from the technology information contained in patent applications.

While the location of such an intellectual property office (within the URSB, the UNCST or elsewhere) is a matter of government choice, it seems essential to ensure that such an office benefits from the expertise available in institutions such as the UNCST, the UIRI 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.

6.3 Legislation

Provisions under the Industrial Property Bill should be interpreted to leave a workable public domain for technological learning, collaborative research and follow-on innovation while at the same time ensuring a balanced system that encourages innovation and promotes legal security. In particular:

Recommendation no. 3: Design of patentability criteria

- Section 11 on 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 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 non-obviousness standard in countries such as the United States;
- In order to maintain researchers' freedom to operate, section 12 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 European Patent Office practice of denying patents on research tools that are claimed for an undefined variety of different uses;
- In case the above interpretations of the inventive step and industrial application standard meet the approval of Ugandan stakeholders, it seems advisable to include them, in express form, in national patent examination guidelines or regulations, or even directly in sections 11 and 12 of the Industrial Property Bill. This would take account of the fact that for PCT applications, the International Preliminary Examination Report is carried out by foreign PCT examiners, who have to rely on written documentation. The sole language used in current sections 11 and 12 on inventive step and industrial application does not reveal how these requirements should be applied to a concrete case.

Recommendation no. 4: Provide inter-policy coherence between patent and other policies

- In order to ensure coherence between patent policy on the one hand, and environment and investment policy on the other hand, the Industrial Property Bill should establish a link between the obligations of a patent applicant to disclose certain information and the technology transfer provisions under the National Environment Regulations and the Investment Code. In particular:
    - Section 21(8) of the Industrial Property Bill (regarding a disclosure of origin and prior informed consent requirement for patent applications based on genetic resources or traditional knowledge) should be amended by providing that the patent applicant should show compliance with section 20 of the National Environment Regulations;
    - A new paragraph should be added under section 21 of the Industrial Property Bill to require that the patent applicant show compliance with the technology transfer provisions under section 30 of the Investment Code.

Recommendation no. 5: Best mode disclosure obligation in patent applications

- Section 39 on disclosure should contain an obligation of the patentee to disclose the best mode for carrying out the invention, known at the time of filing the application. This is an important contribution to helping local innovators and researchers fully understand the technology claimed in the patent.

Recommendation no. 6: Use of patented inventions by researchers

- In order to prevent misunderstandings regarding the scope of the experimental use exemption, section 44(a) (i.e. 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;
- 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, use of the patented invention as a research tool should not be covered by the experimental use exemption, but should be subject to a licence of right from the patent holder. To the limited extent that research tools are patentable under a tight standard of industrial application (see above, Recommendation no. 3 on section 12), patentees should receive remuneration for their use by others, but should not be allowed to prevent access to protected research tools. In this vein, a separate provision should be established, within the Industrial Property Bill, for experiments "with" the patented invention.

Recommendation no. 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 in sections 68(1) and 69(1) of the Industrial Property Bill for purposes of utility models should refer to domestic novelty, as opposed to the novelty standard under patent law.

Recommendation no. 8: Introduce a "use and pay" regime for applications of traditional knowledge and genetic resources

- As an alternative to utility model protection, incremental innovation lacking product novelty and/or an inventive step could also be protected through a use and pay regime, limiting the innovator's exclusivity to two years maximum, followed by a longer period during which the innovator is entitled to remuneration for any improvement uses of his invention. This tool would avoid the blocking effects on the public domain and thereby enable enhanced follow-on innovation, while at the same time providing incentives to domestic innovators. On the other hand, an immediate introduction of an untested 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). In addition, a number of technical details would have to be agreed upon before a use and pay system could be useful in the Ugandan context;
- Taking these considerations into account, the government may 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 investment priority areas of the government.

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

- A robust system of trade secrets protection may provide an appropriate balance between the need to provide incentives to foreign investors and technological first

comers on the one hand, and the need to enable domestic technological learning and follow-on innovation. While exclusive rights protect the inventor, reverse engineering through independent and honest commercial means is permitted and may promote domestic incremental innovation. In order to constitute an effective legal tool, however, it is essential to appropriately allocate the burden of proof in infringement litigation. It seems reasonable to expect the defendant (i.e. the alleged infringer) 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 through the use by the defendant of the protected information should remain valid.

Recommendation no. 10: Ensure licensed intellectual property may be used for technological learning

- The references to IPRs in section 55(2) (s) and (x) of the Industrial Property Bill should be understood as being limited in their scope to those IPRs that are not encompassed in the licensing agreement. A licensee cannot expect to have access to technologies and expertise that is not included in a licensing agreement. As to those IPRs that are actually licensed, the law should not encourage licensors to further limit licensees' rights in a way not consonant with the objective of intellectual property protection under the TRIPS Agreement and the technology transfer provisions under the Investment Code.

Recommendation no. 11: Provide for definitions of intellectual property abuse and certain anti-competitive practices

- In order to facilitate the screening of prohibited terms in technology licensing contracts, section 55 of the Industrial Property Bill should provide definitions of intellectual property abuse, exclusive grantback conditions and conditions preventing challenges to validity (see above, section 5.5). The same definitions could be provided under the (draft) Competition Act.

Notes

[3] See World Bank (2008). Country brief Uganda. September. http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/AFRICAEXT/UGANDAEXTN/0,,menuPK:374947~pagePK:141132~piPK:141107~theSitePK:374864,00.html.

[4] See UNDP (2008). *2007/2008 Human Development Report*: *Country fact sheets – Uganda.* http://hdrstats.undp.org/countries/country_fact_sheets/cty_fs_UGA.html.

[5] See UNCTAD (2004). *An Investment Guide to Uganda: Opportunities and Conditions*. United Nations publication. New York and Geneva: 13.

[6] World Bank (2008).

[7] Ibid., ranking Uganda 125th out of 177 countries.

[8] See Government of Uganda (2007): 2.

[9] See ICTSD (2007).

[10] See UNCTAD (1999). *World Investment Report 1999: Foreign Direct Investment and the Challenge of Development*. United Nations publication. New York and Geneva: 195. See also, Maskus KE (2004). Encouraging international technology transfer. Issue paper no. 7. UNCTAD-ICTSD. Geneva.

[11] UNCTAD (1999): 203.

[12] Ibid.: 196.

[13] UNCTAD-ICTSD (2003). Intellectual property rights: implications for development. Policy discussion paper. UNCTAD-ICTSD. Geneva: chapter 5, 85.

[14] Ibid. See also the introduction to section 5 of this chapter.

[15] See UNCTAD-ICTSD (2005). *Resource Book on TRIPS and Development*. Cambridge, Cambridge University Press: 125–126 and 737–738.

[16] For the following, see in general UNCTAD-ICTSD (2003): chapter 5.

[17] Ibid. and Maskus KE (2005). The role of intellectual property rights in encouraging foreign direct investment and technology transfer. In: Maskus KE and Fink C, eds. *Intellectual Property and Development: Lessons from Recent Economic Research*. Washington DC, World Bank: 41–75 (60).

[18] Interview conducted with Charles Ocici, Executive Director, Enterprise Uganda, 20 May 2008.

[19] See http://www.uncst.go.ug/site/index.php?option=com_frontpage&Itemid=1.
[20] See section 4(e) of the Uganda National Council for Science and Technology Act of 1 June 1990, chapter 209 Laws of Uganda.
[21] Stakeholder discussion on 26 June 2009 with Jeroline Akubu, Principal Legal Officer, Uganda Law Reform Commission; Edgar Tabaro, Legal Consultant, Mwesigwa-Rukutana & Co. Advocates; Dr. Joseph Rubalema, Acting Director Product Development, Uganda Industrial Research Institute; Moses Mulumba, Legal Associate, Kasimbazi, Kamanzi & Co. Advocates; Arthur Mpeirwe, Advocate, Mpeirwe & Co. Advocates; and Anthony C. K. Kakooza, Lecturer, Faculty of Law, Uganda Christian University.
[22] See section 28(1) of the Uganda Registration Services Bureau Act.
[23] See section 4(1)(a) of the Uganda Registration Services Bureau Act.
[24] See ibid., section 4(2)(a).
[25] Stakeholder discussion on 26 June 2009.
[26] Ibid.
[27] See http://www.uiri.org/index.php.
[28] For example, the National Agricultural Research Organization (see at http://www.naro.go.ug/).
[29] Ministry of Finance, Planning and Economic Development (2007). *National Science, Technology and Innovation Policy: Final Draft*; approved in August 2009 (interview with Julius Ecuru, Assistant Executive Secretary, UNCST, 11 November 2009).
[30] Ministry of Finance, Planning and Economic Development (2007): 16.
[31] Ibid.: 17 and 35 (annex 1).
[32] In this context, the UNCST/UIRI-sponsored MSI project, as discussed above, could provide some important inputs into the new policy.
[33] UNCTAD-ICTSD (2003): 85–86.
[34] Interview with Tom Buringuriza, Deputy Executive Director, Uganda Investment Authority, 15 May 2008.
[35] See UIA (2007). Report of the Presidential Investors Round Table Meetings – 2004/6. Kampala.
[36] For example, interview with Professor Charles G. Kwesiga, Executive Director, UIRI, 19 May 2008.
[37] ICTSD (2007): 20–21.
[38] Interview with Cyprian Batala, Assistant Commissioner, Ministry of Tourism, Trade and Industry, 14 May 2008.
[39] See Ugandan factory starts producing AIDS drugs, press report at http://www.iqpc.co.za/News.aspx?id=126790075&IQ=pharma; further information from an interview with George Baguma, Marketing Director, Quality Chemicals Industries Ltd., 17 May 2008, and from http://www.pharmaceutical-technology.com/projects/qualitychem/.
[40] Interview with George Baguma on 10 November 2009.
[41] Ibid.
[42] Ibid.
[43] See *Business Week* (2008). Cheap AIDS drugs bring Uganda hope. 14 July.
[44] See Baguma G (2008). Expanding access to essential medicines in least developed countries through local manufacturing: Uganda's experience. Slide no. 18. http://www.africacncl.org/Events/downloads/2008_PSHF/Baguma, per cent20George.pdf.
[45] Interview with George Baguma.
[46] Ibid.
[47] See Ugandan factory starts producing AIDS drugs, press report at http://www.iqpc.co.za/News.aspx?id=126790075&IQ=pharma.
[48] *Business Week* (2008): 1–2.
[49] Interview with C. G. Kwesiga.
[50] Ibid., referring to his presentation Kwesiga CG (2007). Role of incubation in enterprise development. Presentation of 13 July (on file with the authors).
[51] See Kwesiga (2007): 9.
[52] See http://www.uiri.org/index.php?page=page21.
[53] Interview with C. G. Kwesiga.
[54] See Swedish International Development Agency (SIDA) and BIO-EARN (2006). Biotechnology and the future of Africa: a presentation of the BIO-EARN programme.
[55] See Bio-Earn (2008). Managing intellectual property: Eastern African universities and research institutes can do more to help scientists. Policy brief 1: 2.
[56] See UNCST/UIRI (2008). MSI Uganda Millennium Science Initiative: call for proposals. 4. These grants are based on funding made available by the World Bank Group, see Wamboga-Mugirya P (2006). US$30m "Millennium Science Initiative" for Uganda. http://www.scidev.net/en/news/us30m-millennium-science-initiative-for-uganda.html.
[57] See UNCST/UIRI (2007). Uganda MSI Component 1: Window C. Private Sector Cooperation Manual: 4–5.
[58] See MSI call for proposals response analysis. http://uncst.go.ug/site/index.php?option=com_content&task=view&id=45&Itemid=54. This source contains no preliminary analysis on submitted proposals related to university-industry cooperation in technology development, where various grants of up to $50,000 were made available (see ibid.).
[59] Ibid.

[60] According to information provided by UIRI staff in June 2009, the call for proposals has received only a low response, and the submitted proposals are of low quality. According to this source, the level of technological capacity revealed in these proposals is very disappointing.
[61] See http://uncst.go.ug/site/epublications/research_registration/intro1.htm.
[62] See section 3.0 of the Guidelines.
[63] Ibid.
[64] See section 21(b) of the Regulations.
[65] See sections 20(2), 14(1) and 7(1) of the Regulations.
[66] See section 10(1) of the Investment Code.
[67] See section 12(d) of the Investment Code.
[68] UIA (2007). *The Report of the Presidential Investors Round Table Meetings – 2004/6.* Kampala.
[69] Interview with C. Ocici. .
[70] See section 15(1)(c) of the Investment Code.
[71] Stakeholders' meeting on 25 June 2009.
[72] See section 18(2)(b) of the Investment Code.
[73] Interview with C. Ocici.
[74] Interview with T. Buringuriza.
[75] Available at http://www.ict.go.ug/policy.html.
[76] Ibid.
[77] Ibid.: 35.
[78] Ibid.: 26.
[79] See, for instance, UNCTAD-ICTSD (2003): chapter 5; see also UNCTAD (1997). *The TRIPS Agreement and Developing Countries*. United Nations publication. New York and Geneva; in particular section IV: 21–22.
[80] UNCTAD-ICTSD (2003): chapter 5. Interviews with various stakeholders confirmed the importance for Uganda of informal means of technology transfer. See also ICTSD (2007): 20.
[81] Government of Uganda (2007): 5.
[82] See ICTSD (2007): 20.
[83] Ibid.
[84] Uganda, as an LDC, is granted a transition period until 1 July 2013 for the general application of the TRIPS provisions (except the obligation to respect national and most-favoured nation treatment). See WTO (2005). Decision by the TRIPS Council of 29 November 2005: extension of the transition period under article 66.1 for least developed country members. IP/C/40. 30 November. Uganda is also granted an additional transition period until 1 January 2016 for the implementation of the TRIPS provisions on patents and undisclosed information (including clinical test data) in the area of pharmaceutical products. See WTO (2002). Decision by the TRIPS Council: extension of the transition period under article 66.1 of the TRIPS Agreement for least developed country members for certain obligations with respect to pharmaceutical products. IP/C/25. 27 June. For a more detailed analysis, see chapter II in this report.
[85] For an example of how countries may successfully adjust their domestic intellectual property systems to their changing levels of development, see, Kim L (2003). Technology transfer and intellectual property rights: lessons from Korea's experience. Issue paper no. 2. UNCTAD-ICTSD. Geneva (http://www.iprsonline.org/resources/docs/Kim%20-%20ToT%20and%20IPRs%20-%20Blue%202.pdf).
[86] OECD, Working Party of the Trade Committee (2003). The impact of trade-related intellectual property rights on trade and foreign direct investment in developing countries. (http://www.oecd.org/dataoecd/59/46/2960051.pdf).
[87] Interview with Kyomuhendo Bisereko, Registrar General, Uganda Registration Services Bureau, 14 May 2008.
[88] See section 3(6) of the Harare Protocol, which takes into account that ARIPO examiners cannot be expected to be aware of all the particularities of member States' intellectual property legislation.
[89] Ibid.
[90] For the PCT procedure, see http://www.wipo.int/treaties/en/registration/pct/summary_pct.html.
[91] Supreme Court of the United States (2007). *KSR International Co. v. Teleflex Inc. et al.* 550 U.S. (2007).
[92] Very broadly speaking, research tools are devices used by researchers to discover unknown properties of existing products or to assist in the development of new products. Depending on the area of technology, research tools are essential for technological innovation. For instance, in the pharmaceutical sector, research tools may consist of a gene or a part of a gene that can be used to help identify unknown genes and to map their positions within a genome, in a quick and inexpensive fashion. See http://www.ncbi.nlm.nih.gov/About/primer/est.html.
[93] In European Patent Office practice, such exclusions are based on the understanding that the industrial application standard requires the existence of an industrial product, as opposed to purely experimental research tools.
[94] See Government of Uganda (2007): 5.
[95] ULRC (2004a). *A Study Report on Industrial Property Law (Patents, Industrial Designs, Technovations and Utility Models)* (Law Com Pub. No. 12 of 2004). Kampala.

[96] See UNCTAD (2008). Comparative study of provisions of EAC partner States' patent laws reflecting TRIPS flexibilities relevant for the access to medicines. UNCTAD. Geneva (on file with the authors). The study was prepared for Germany's technical cooperation agency GTZ, upon request from the Secretariat of the EAC.
[97] Ibid., section on scientific research exception.
[98] See Industrial Property Bill 2004, as provided in ULRC (2004a): 91.
[99] In its EAC study, UNCTAD recommended the insertion of express language into section 44(a), clarifying that this provision only authorizes uses for the purpose of generating new knowledge (as opposed to reverse engineering of the existing product).
[100] See http://www.admin.ch/ch/f/rs/232_14/a9.html for the official French language version and http://www.admin.ch/ch/d/sr/232_14/a9.html for the official German language version; an official version in the English language is not available.
[101] See Thumm N (2007). A statutory research exemption for patents. In: Pugatch MP and Jensen A, eds. *Healthy IPRs: A Forward Look at Pharmaceutical Intellectual Property*. London, Stockholm Network: 116–129.
[102] See *CoreValve Inc v Edwards Lifesciences AG & anr [2009] EWHC 6 (Pat)*. (for a brief analysis of this decision, see http://www.sjberwin.com/html_newsletters/ebf/pharma/pharma_update/March2009/article2.html.
[103] See UNCTAD (2008): footnote 115.
[104] See article 40b of the Swiss Patent Act, as entered into force on 1 July 2008 (French language version available at http://www.admin.ch/ch/f/rs/232_14/).
[105] Interview with Dr. Charles Ibingira, Deputy Dean Research, Makerere Medical School, 15 May 2008.
[106] The Bayh-Dole Act introduced the possibility for United States universities to be granted patent protection for inventions resulting from publicly funded research.
[107] See So A *et al.* (2008). Is Bayh-Dole good for developing countries? Lessons from the US experience. PLoS Biology 6 (10): e262. (http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2573936).
[108] For a discussion of the pros and cons of Bayh-Dole types of legislation, see below.
[109] See UNCTAD (1985). Draft International Code of Conduct on the Transfer of Technology as of 5 June 1985. TD/CODE/TOT/47.
[110] Ibid.
[111] See Reichman JH (2003). Non-Voluntary licensing of patented inventions: historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the United States of America. Issue paper no. 5. UNCTAD-ICTSD. Geneva: 21 (http://www.iprsonline.org/unctadictsd/projectoutputs.htm#casestudies).
[112] See UNCTAD-ICTSD (2005): 548.
[113] See footnote to section D, para. 4 of the Set of Multilaterally Agreed Principles and Rules.
[114] See Bio-Earn (2008): 2.
[115] Ibid.
[116] So *et al*.: 1.
[117] Interview with C. Ibingira.
[118] So *et al.*
[119] Ibid.
[120] See Sampat BN (2009). The Bayh-Dole model in developing countries: reflections on the Indian bill. Policy brief on the WIPO Development Agenda. UNCTAD-ICTSD. Geneva (http://www.unctad.org/tot-ip).
[121] Ibid.: 7, quoting Bulut H and Moschini G (2006). US universities' net returns from patenting and licensing: a quantile regression analysis. Working paper. Iowa State University (http://ideas.repec.org/a/taf/ecinnt/v18y2009i2p123-137.html).
[122] Ibid.: box 1.
[123] See the explanation of the Australian "Innovation Patent" at http://www.ipaustralia.gov.au/patents/what_innovation.shtml#1.
[124] See section 23.1 of the German law on utility models (Gebrauchsmustergesetz).
[125] See Reichman JH (2000). Of green tulips and legal kudzu: repackaging rights in subpatentable innovation. *Vanderbuilt Law Review.* 53: 1753.
[126] See Reichman JH and Lewis T (2005). Using liability rules to stimulate local innovation in developing countries: application to traditional knowledge. In: Maskus KE and Reichman JH, eds. *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime.* Cambridge, Cambridge University Press: 337–366.
[127] See Reichman and Lewis (2005): 349–351.
[128] Ibid.
[129] Reichman (2000): 1784.
[130] This Act is available at http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=5242.
[131] See section 4 of the 2009 Trade Secrets Protection Act.
[132] Article 10*bis* of the Paris Convention has also been the foundation for the provisions on the protection of regulatory test data under article 39.1 of the TRIPS Agreement. See UNCTAD-ICTSD (2005): 523, and chapter II of this report.
[133] See sections 5(2) and 7(b), (c) of the 2009 Trade Secrets Protection Act.

[134] See Goulet P (2004). Burden of proof and the defence of independent development in trade secret litigation. http://www.thefreelibrary.com/Burden+of+Proof+and+The+Defence+of+Independent+Development+in+Trade...-a0112456709.

[135] Ibid., with examples of divergent decisions.

[136] Under this approach, the assertion of independent development by the defendant shifts the burden of going forward (i.e. of producing the next relevant evidence) onto the defendant, who will have to show his substantial capacity. However, the final burden of persuasion remains with the plaintiff, who subsequently will have to persuade the court that the use of the secret in the particular case was not through independent means. See Goulet (2004).

[137] This holds true despite the fact that normally, the defendant would have to furnish relevant information to the plaintiff to facilitate the latter's task. The defendant may hold back some of that information, and the plaintiff, due to his unfamiliarity with the defendant's internal modes of operation, is not in a position to claim specific pieces of information needed to discharge the burden of proof (Goulet, 2004).

II. Intellectual Property and Access to Medicines

1. Introduction

As of 2007/2008, Uganda is positioned 154th on the UNDP Human Development Index.[138] Life expectancy at birth is 48 years for males and 50 years for females, and 31 per cent of the population lives below the poverty line.[139] While adult HIV prevalence peaked at 18 per cent in 1992, this rate has been considerably reduced, to 6.4 per cent in 2007.[140] However, this positive development has been reversed since about 2002, with rising infection rates between 0.2 per cent and 2 per cent in different regions of the country.[141] The Ministry of Health (MoH) has been quoted as estimating that by 2020, 342,200 Ugandans will be in need of anti-retroviral treatment (ART), as compared to 234,500 in 2006.[142]

Different stakeholders estimate that between 34 per cent[143] and 42 per cent[144] of those individuals in need of ARVs are actually reached. WHO figures for September 2007 refer to 121,200 individuals as having access to ARVs, out of a total of some 312,000 in need.[145]

The issue of access to medicines in Uganda is much broader than the HIV/AIDS crisis. According to the WHO, "malaria is the leading cause of morbidity and mortality in Uganda and is responsible for up to 40 per cent of outpatient visits, 25 per cent of hospital admissions and 14 per cent of hospital deaths. The burden of malaria is greatest among children under five years of age and pregnant women."[146]

Another problem is access to tuberculosis treatment. In this respect, the WHO has recently stated that:

> The treatment success rate remains low because of the high proportion of patients who die, default from treatment or for whom the treatment outcome is not evaluated. Training on collaborative TB/HIV activities based on standardized national guidelines has been provided to around half of the districts. Inadequate funding, linked in part to problems with disbursement of Global Fund grants, has hampered the progress of the national programme. Shortages of first-line anti-TB drugs have also been reported.[147]

Finally, the country faces frequent outbreaks of serious tropical diseases, such as, in particular, Ebola haemorrhagic fever between 2000 and 2008.[148]

The interface between IPRs and access to medicines is complex and multi-faceted. While Uganda as an LDC currently benefits from a waiver of the obligation to implement the TRIPS provisions on patents and undisclosed information (including clinical test data) in the area of pharmaceutical products until 1 January 2016, the country's Universal Drug Access Policy relies to a large extent (80 per cent) on imported drugs,[149] which may be patented abroad.

IPRs constitute important incentives for innovation[150] and for the marketing of pharmaceutical products, but their benefit may not be the same for all types of diseases, as demonstrated by the disproportionately low investment in innovation for diseases that affect the poor in developing countries.[151] IPRs may also create obstacles to future innovation and impediments to the diffusion of both knowledge and research results in addition to high prices that reduce access to needed medicines.[152] Experts have highlighted that exclusive rights are one important factor among others influencing the prices of pharmaceutical products.[153] This premise has also been acknowledged in the WTO Declaration on the TRIPS Agreement and Public Health, whose paragraph 3 states: "We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices."[154]

Considering that as of 2016, Uganda will have to implement the TRIPS provisions on patents and undisclosed information,[155] it is therefore important to make domestic implementing legislation compatible with the overall stated goal of the country's National Drug Policy: "to contribute to the attainment of a good standard of health by the population of Uganda, through ensuring the availability, accessibility and affordability at all times of essential drugs of appropriate quality, safety and efficacy, and by promoting their rational use."[156]

This being said, it is equally important to emphasize the multifaceted and pluri-disciplinary character of public health policies. Access to medicines can only be effectively promoted through a holistic approach, taking account of all factors including those related to intellectual property. This chapter will seek to do so, to the extent possible under the terms of reference contained in the request by MTTI (see sections 4 and 5 of this chapter, below).

2. Institutional set-up and objectives of the government

There are several institutions that are involved in the design of Uganda's public health policies. The MoH provides health-related policies, guidance and standards in general.[157] Then MoH is a co-owner of the Joint Clinical Research Centre (JCRC), an incorporated company that undertakes medical research and provides training and health care services (including drugs procurement), especially in the area of HIV/AIDS.[158]

As far as specific AIDS policy is concerned, the Office of the President has established, under its auspices, the Uganda AIDS Commission (UAC). The UAC oversees, plans and coordinates AIDS prevention and control activities throughout Uganda.[159] It has been mandated, inter alia, to formulate, plan and coordinate AIDS-related policy, establish treatment programme priorities and identify obstacles to the implementation of AIDS policies and programmes.[160]

Uganda's National Health Policy, adopted in 1999, emphasizes the close interface between health on the one hand and sustainable development and poverty eradication on the other.[161] In turn, Uganda's Poverty Eradication Action Plan includes, inter alia, a pillar on "Human Development", which addresses strategies for combating HIV/AIDS.[162]

In accordance with the overall goal enunciated in the country's National Drug Policy (see above), the Ugandan Government has committed itself to providing free ARV and artemisinin (i.e. anti-malarial) products to all those in need.[163] The availability of affordable drugs is an important policy goal that cuts across a number of policy areas covered by the National Drug Policy. In this respect, it is interesting to note that some emphasis is put upon the local production of generic pharmaceutical products, as well as the use of generic drugs (locally produced or imported) for the purposes of both drugs procurement and drugs pricing. In particular, the objectives of drugs procurement are, inter alia:

> 3. To ensure the procurement of generic drugs in the public sector and encourage this in the private sector.
> 4. To maximize appropriate procurement of locally produced essential drugs.[164]

Accordingly, the National Drug Policy contains the following strategies:

> 7. Encourage the private sector to procure drugs so as to complement the public sector procurement system, e.g. procurement of *essential* drugs by *generic* name. (emphasis in original)
> 8. Encourage local pharmaceutical manufacturers to produce essential drugs at competitive prices and encourage procurement agencies to source available essential drugs locally in order to support the local industry.[165]

With respect to drug pricing the objective is "to maintain consumer prices of essential medicines available in the country at the minimum possible using all available options."[166]

Among the strategies to reach this objective, the National Drug Policy provides, inter alia, to:

> 3. Actively promote the concepts and practice of generic prescribing and appropriate generic substitution as a means of minimizing drug costs.
> 4. Ensure that the implications of the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO/TRIPS Agreement) are well publicized and understood by the relevant policymakers.[167]

Section 5 of this chapter seeks to provide some guidance on how to design Uganda's regime on patents and pharmaceutical clinical test data protection in a way that is conducive to these objectives and strategies.

3. Pharmaceutical product procurement and research, and main obstacles to general access to medicines

The Government of Uganda sponsors about half of all ARVs procured in the country. This is approximately equivalent to 20 per cent of the total need, since the total coverage of ARVs through all sources was only between 34 per cent and 42 per cent of the total need as of 2007/2008 (see the introduction to this chapter). Due to limited government resources, the MoH and the JCRC have been dependent to a great extent on contributions from foreign donors, mostly through the provision of funds required to procure ARVs and other medicines.[168] In their procurement activities, the MoH and the JCRC source about 80 per cent of the medicines abroad, with 50 per cent of these products coming from Asia. The MoH staff estimate that 90 per cent of the drugs provided by the government are generic medicines, to address financial constraints. There are efforts to increase the percentage of locally produced medicines in the public procurement process; eight billion Ugandan Shillings (USH) (approximately $4,006,000[169]) were committed in the financial year 2008 to procure medicines from the new Cipla/Quality Chemicals joint venture.[170] This joint venture, which is described in detail in chapter I of this report, started production of ARVs on 19 February 2009. While it is planned to produce drugs at $9 per month per patient,[171] the prices currently charged for Quality Chemicals products are higher than those at which imported Indian generics, including Cipla's own products, are presently available in Uganda.[172] In addition, stakeholders have noted the dilemma caused by the impact of foreign donations of medicines (such as, for example, through philanthropic actions) on local competitive production.[173] Considering the dependence of the joint venture on government procurement, donations to the government could potentially crowd local producers out of the market, as even their low prices cannot compete with donations.

Another important development relates to the successful establishment in Uganda of some infrastructure to carry out scientific research on HIV/AIDS. The JCRC and Makerere University are important actors in this regard.[174] In particular, Makerere Medical School has the capacity to perform chemical testing to help the National Drug Authority to approve generic drugs.[175] For these purposes, the school receives drug samples from foreign and local companies.[176]

The reasons for which only parts of the population in Uganda have access to medicines, and, in particular, ARVs, are multifold. Based on interviews with stakeholders and publicly available information, there seem to be four major reasons, namely: poor health care infrastructure; weak management of public funds; underfunded drug quality control systems; and high prices of procured pharmaceutical products.

The first two reasons – poor health care infrastructure and weak management of public funds – seem to be closely linked. Procurement and distribution of drugs by the National Medical Stores have been characterized as the weak point in Uganda's health care system.[177] Reportedly, bureaucracy problems, political interference, shortages in drugs storage space, stock-outs and a "chronic lack of manpower" have hampered an efficient functioning of the National Medical Stores and have resulted in incomplete and irregular drug supplies.[178] In 2005, grants made to Uganda through the Global Fund to Fight AIDS, Tuberculosis and Malaria were suspended after findings of gross mismanagement of the funds through a government agency, resulting in severe drug stock-outs.[179] In addition, HIV/AIDS clinics that provide treatment are often out of reach for many of the needy.[180]

With respect to underfunded drug quality control systems, according to the WHO, drugs quality control in Uganda is weak,[181] which could explain a reported preference among many Ugandans of OECD-sourced brand name or generic drugs over locally produced ones.[182] As highlighted in section 4.2 of this chapter, the technical capacity of Ugandan drug regulators is satisfactory; the problem seems to be related to a lack of funding, despite very encouraging developments over the past years (see section 4.2 for details).

Finally, the high prices of procured pharmaceutical products are a limiting factor as far as foreign products are concerned. The JCRC, in its procurement activities, meets with increasing difficulties to purchase foreign-sourced, innovative second line ARVs, due to drug prices that are viewed as being too high.[183] Senior JCRC staff considers that the lack of generic competition in second line ARVs – which are mostly patented in the source OECD countries – explains the high prices of these drugs. This has led to delays in switching patients from first to second line treatments and has caused the development of drug resistance in some patients.[184] Serious concern has also been expressed by stakeholders and the WHO about the costs faced by patients to benefit from HIV testing.[185] Accessibility by public procurers such as the JCRC to HIV testing kits is reportedly limited by the high prices charged by OECD-based owners of patents on these kits.[186]

The National Drug Policy, by emphasizing in its objectives and strategies the local production of pharmaceuticals,[187] does not seem to rely primarily on continued funding from foreign donors, or on philanthropic action such as drug donations on the part of foreign pharmaceutical companies. As important as these activities are in the short run, they may be discontinued at the donor's discretion, may be limited in time and thus do not necessarily contribute to a country's long-term public health security in terms of continuous supplies. In a 2007 publication, HEPS-Uganda quotes the MoH as stating that the external sources on which the country's HIV/AIDS response has depended are "unpredictable and unsustainable".[188] Likewise, local health workers have reportedly expressed serious concerns about the dependence of Uganda's HIV/AIDS strategy on foreign funding, such as the HIV/AIDS Focal Person for the Soroti District:

> We now depend entirely on outside funding since the local revenue that used to be collected through graduated tax is no longer there. So if say tomorrow, AIM [the AIDS/HIV Integrated Model District Programme], UPHOLD, Red Cross among others decided to close, there would not be any other source for the district, especially now that we almost entirely depend on outside funding.[189]

In this context, civil society has also emphasized the increasing demand for ARVs in Uganda, which would "far [outstrip] the capacity of the response system and available financing".[190] HEPS-Uganda quotes the Ugandan Finance State Minister, according to whom the expenses for procuring imported medicines rose from $3 million in 2004/05 to $54 million in 2007/08.[191] In this context, HEPS-Uganda refers to the increased difficulties faced by generic producers in Brazil, China and India to supply Uganda with low-priced drugs, due to their governments' obligation to implement the TRIPS Agreement.[192]

4. Legislation, guidelines and policies related to access to medicines and drug regulation

While the scope of the present analysis is mainly limited to intellectual property issues,[193] the above-mentioned factors inhibiting access to medicines in Uganda show that a sound public health policy framework needs to look beyond intellectual property in order to provide an environment conducive for access. While it would go beyond the scope of this report to provide for an exhaustive analysis of all non-intellectual property elements in Uganda's public health policy, this section will address those aspects that also have some implications for the design of the country's intellectual property legislation. Specific intellectual property issues will then be dealt with under the next section.

4.1 Drugs prices and local production

As observed above, the main obstacles to general access to medicines in Uganda are a weak infrastructure and poor management of public funds, weak drug quality control and the price of foreign pharmaceutical products needed for government procurement. Addressing the price issue first, local stakeholders have expressed the hope that local pharmaceutical producers in Uganda could bring down prices for ARVs as compared to imported drugs.[194] The only producer currently making generic ARVs in Uganda is the above-mentioned Cipla/Quality Chemicals joint venture.

While the joint venture has succeeded in launching actual production of ARVs and anti-malarials in Uganda, a host of challenges remain to ensure its success in the future. Above all, there is the issue of price. For the time being, the drugs produced under the joint venture are still more expensive than imported Indian generics, including Cipla's own products. This means that, even if the joint venture succeeded in being granted WHO pre-qualification status, its products would nevertheless be too expensive to win international tenders. It is questionable whether under such a scenario, current plans to become a regional exporter of pharmaceuticals are realistic and provide a sufficient basis for economically viable, long-term production.[195]

A key element in reducing costs is to make the joint venture less dependent on the importation of all the needed pharmaceutical ingredients, especially the APIs. For this reason, Cipla is considering setting up an R&D centre at the Luzira plant.[196] However, the company seems to make this decision dependent on certain amendments to the existing Ugandan patent law. Senior Cipla staff have especially voiced concern regarding a pending implementation, by the Ugandan legislature, of the TRIPS Agreement "mailbox" provision.[197] According to that provision, applications for pharmaceutical patents filed before the end of the above-mentioned LDC transition period (i.e. 1 January 2016) cannot be entirely ignored, but would have to be examined and, depending on the case, granted after 1 January 2016. This may affect Cipla's possibilities to use a number of pharmaceutical substances in the context of the envisaged local API production at Luzira.[198] While Cipla has highlighted the importance of refusing implementation of the mailbox obligation under Ugandan patent law, the Industrial Property Bill of 2009 contains a mailbox provision (see section 5.1). The present report recommends an amendment to this provision, because Uganda is not obligated, under the TRIPS Agreement, to implement a mailbox.

Another important issue affecting the future success of the joint venture, especially in carrying out pharmaceutical research and development activities, is the capacity of local staff to actually absorb the technology that is being offered by Cipla. According to Cipla personnel, Ugandan human resources currently available are not satisfactory due to a lack of qualified pharmacists.[199] Interviews conducted by UNCTAD in November 2009 revealed a serious lack of linkages between universities and research institutes on the one hand, and the industry on the other.[200] Local stakeholders identified a number of reasons for this, such as:

- Universities do not have functional intellectual property/technology management policies and thus have a very limited notion of how to collaborate with industry;
- Limited skills in the private sector to write grant proposals for technology development. The private sector is focused on quick benefits, but less interested in long-term (e.g. 15 years) technology development initiatives;
- There seems to be an ivory tower mentality at universities, resulting in a lack of motivation of university staff to engage in new activities on commercialization.[201]

On the part of the government, there has been no overall strategy of technology commercialization (see also chapter I). In particular, the Cipla/Quality Chemicals joint venture was never considered an opportunity for the development of local capacities in pharmaceutical technology, but a pure matter of public health and investment. Research institutes have never really focused on the development of pharmaceutical technologies, but on traditional areas of Ugandan comparative strength, such as coffee and fish.[202] While the National Science, Technology and Innovation Policy was approved in August 2009, it is very broad and does not specifically refer to pharmaceuticals.[203]

It is against this background that the government should evaluate suggestions to provide local pharmaceutical producers with temporary protection from overwhelming foreign competition. Suggested measures include preferential treatment of local producers in medicines procurement, higher import tariffs on finished pharmaceutical products and improved access to capital for local producers.[204]

These suggestions deserve careful consideration, especially in light of the important potential public health and industrial development benefits that could possibly result from a viable pharmaceutical manufacturing site in Uganda. However, the protection of domestic producers against foreign competitors only makes sense to the extent that the domestic manufacturer is capable of producing quality products that meet WHO pre-qualification requirements, i.e. quality, safety and efficacy of the products, as well as compliance of the manufacturing site with GMP, or at least domestic quality and GMP standards that guarantee safe and efficacious medicines.[205] In addition, production has to be economically viable, which means overcoming the difficulties described above in terms of uncompetitive prices and unqualified local personnel.

4.2 Regulation of and compliance with drug quality standards

Effective drug regulation and compliance with regulatory standards play a key role in the promotion of domestic high quality medicines. In this context, the degree of independence of the national drug regulatory agency and the extent to which it is capable of quality controlling medicines plays a key role. According to information received from WHO staff as well as the Executive Secretary/Registrar of Uganda's National Drug Authority (NDA), the current situation at the NDA in Uganda may be summarized as follows:[206]

- The NDA is established under the National Drug Policy and Authority Act, chapter 206 Laws of Uganda as an autonomous corporate body with perpetual succession. It has the power to recruit, hire and fire its own staff;
- According to the WHO, the available technical skills are satisfactory;
- As compared to other developing countries, staff fluctuation is low;
- Between 2001 and 2008, the share of foreign donor support in NDA sources of funding has been decreasing, while the share of own revenue from services fees has been increasing considerably.
    - In 2007/08, 92 per cent of the NDA's revenue came from internal sources, 8 per cent was donor-supported and 0 per cent government-funded;
    - The main sources of internally generated revenue are drug registration and retention fees, inspection and licensing fees for distribution outlets, drug import verification fees, GMP inspection fees and analysis fees (drug samples,

condoms and long-lasting insecticidal nets). These fees are regularly reviewed in consultation with stakeholders;[207]

- However, as in most developing countries, the WHO still considers the authority to be underfunded.[208]

The NDA's activities are not limited to drug quality control at the time of drug registration, but include, for instance, post-marketing surveillance, the inspection and licensing of drug outlets and the regulation of drug-related clinical trials. However, in its present state, with severe funding (and related staff) limitations, it is unclear if the NDA can perform these tasks.

In order to ensure the continuation of these encouraging developments, it seems essential for the NDA to continue receiving the bulk of its revenue from services fees, making it independent from foreign donor or government funding. An important element in these efforts is continuous consultation with stakeholders to ensure fees, while supporting the NDA's activities, do not overburden domestic companies. On drug testing, the NDA should make sure it applies the same procedural requirements for locally produced drugs as it is applying to imported drugs, in order to ensure uniform quality of all medicines sold in the market.

Having discussed some features of Uganda's drug manufacturing facilities and the country's drug regulatory system, the last section of this chapter will seek to identify those elements in the national intellectual property framework that could potentially contribute to the overall goal stated in Uganda's National Drug Policy, i.e. the "availability, accessibility and affordability at all times of essential drugs of appropriate quality, safety and efficacy". In this context, it should be borne in mind that any changes to the domestic intellectual property system can only have a real impact on access to medicines if addressed in tandem with the issues discussed under the present section.

5. Analysis of the intellectual property legislative framework relevant to access to medicines (patents and pharmaceutical test data)

The implications of IPRs on access to medicines largely depend on the way a given country sources its medicines supplies for its public health programmes. Countries that have relatively large health budgets and are the home of technologically advanced, R&D-based pharmaceutical companies are likely to welcome the benefits of exclusive rights on pharmaceutical innovation. However, even in those countries, increasingly constrained public health budgets, coupled with the perception that despite exclusive rights, the innovative performance of the R&D-based industry has been disappointing in recent years, have resulted in intense debates as to what extent exclusive rights in pharmaceuticals should be limited to promote generic competition.[209]

This debate is even more valid in developing countries and especially LDCs such as Uganda, where government resources are much more limited and where drug prices are one among several factors determining the success or failure of a national health policy. In addition, arguments regarding the need for the R&D-based industry to recoup R&D expenses through intellectual property royalties seem less convincing in the developing country context, as these expenses may be considered to be largely recouped in wealthy OECD markets.[210] For Uganda in particular, it also has to be borne in mind that the bulk of the drugs purchased by the MoH and the JCRC are already generics (see above), which should be reflected in the country's intellectual property legislation. Finally, the considerations made in chapter I also apply in the pharmaceutical context: countries seeking to establish domestic technological capacity (be it in the pharmaceutical sector or others) must to empower domestic 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 analysis of Uganda's relevant intellectual property legislation will be guided by the understanding that a substantial amount of operating space should be maintained for the producers of generic pharmaceuticals, enabling both affordable drugs prices and domestic technological learning. While the need to protect and encourage innovation is paramount, considerations related to transfer and dissemination of technology, the protection of public interests and the promotion of a pro-competitive environment are important for making the system relevant and appropriate in an environment like that in Uganda.

Relevant legislation in this regard is the Industrial Property Bill (as of 28 November 2007), the National Drug Policy and Authority Act 1993 (chapter 206 Laws of Uganda), the Guidelines on Registration of Pharmaceutical Drugs for Human Use in Uganda (revised 2001) and the Counterfeit Goods Bill 2008. As far as the Industrial Property Bill is concerned, reference is made to the analysis under chapter I. The present section will be limited to those provisions in the bill that have not been examined before, and which are of particular relevance in the access to medicines context.

5.1. LDC transition periods (Section 8, Industrial Property Bill)

In the Industrial Property Bill, Uganda has chosen to implement the 2016 transition period for pharmaceutical products.[211] Pharmaceutical products are not considered as patentable inventions before 1 January 2016 and are excluded from patent protection until that date (section 8(3)(f)).[212] As stated in chapter I, Quality Chemicals' Finance Director considers the possibility of making generic copies of pharmaceutical substances that are patent-protected abroad as one of the decisive incentives for the joint venture to have located the new production site in Uganda. It follows from the Industrial Property Bill (section 8(3)(f)) that after its entry into force, new pharmaceutical product patents will not be granted, nor will existing ones be enforced, before 1 January 2016. In this context, the bill (section 8(3)(f)) should be read in conjunction with related provisions of the bill, namely section 28(13) and (14) dealing with the "mailbox" obligation (see box 1).

Box 1. Section 28(13) and (14) of the Industrial Property Bill: the "mailbox" obligation

(13) Subsection (1) [i.e. filing of the patent application] shall apply to the inventions mentioned in section 8(2) [sic] (f) immediately after the coming into force of this Act.

(14) The remaining subsections of this section as well as section 32 [i.e. grant, registration and publication of a patent] shall apply to the inventions mentioned in subsection (13) only after January 1, 2016; and the examination of those inventions shall apply the conditions of patentability referred to in subsection (4) [sic] as if those conditions were being applied on the date of filing in Uganda, as established under subsection (1), or where priority was claimed, the priority date of the applications.

This provision, as reproduced in the box, implements the so-called "mailbox" obligation under article 70.8, TRIPS Agreement. 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.[213] 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.[214] For generic producers, this may have important implications, as products they have used during the transition period may become subject to a patent once the transition period expires in 2016. This is precisely what has apparently caused concern among generic investors in Uganda, as pointed out above (section 4.1). Without such a mailbox provision, a patent for a substance available to the public before 2016 would not be granted due to lack of novelty.

In principle, the mailbox obligation under article 70.8 of the TRIPS Agreement applies to the 2016 LDC transition period on pharmaceutical products as well as to the more general 2013 LDC transition period.[215] However, the obligation to implement the mailbox is expressly limited to those members that do "***not*** make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products".[216] Uganda in its Patents Act of 1993 provides for the protection of patents, including pharmaceutical products.[217] Thus, the mailbox obligation under article 70.8 of the TRIPS Agreement does not apply to Uganda, and the mailbox as contained in section 28(13) and (14) of the bill goes beyond what Uganda is required to do under the TRIPS Agreement.[218] Considering the potential impact of a mailbox provision on the availability for generic producers of pharmaceutical substances after 2016, as well as the concerns expressed by a major Indian investor (see section 4.1), 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.

Finally, with respect the transition period, it is important to note that according to the TRIPS Council Extension Decision of 2002, the 2016 deadline may be further extended by the council upon request by LDC members.[219] Civil society has criticized the Industrial Property Bill for not having included a reference to a possible extension of the transition period by the TRIPS Council, thus requiring further legislative action in case an extension is eventually granted.[220]

5.2. **Administrative opposition procedures** (Section 28(7), Industrial Property Bill)

The bill (section 28(7)) provides that interested third parties may oppose a patent application within 90 days after it has been published. As far as pharmaceutical products are concerned, this provision will only generate its effects after the end of the transition period in 2016. Considering the amount of poor quality pharmaceutical patents even in OECD countries,[221] and in addition the prohibitive costs of patent litigation before the courts, a simple and low-cost administrative procedure provides an important tool for generic competitors and public interest groups to help prevent the granting of overly broad and poor quality patents.

As stated chapter I, most patent applications in Uganda are channelled through ARIPO, which carries out the substantive examination for all patent applications, even those that are directly filed at the national intellectual property office and then transmitted to ARIPO.[222] In order for the opposition procedure to be effective, oppositions should be sent to the URSB, before the latter forwards the patent application to ARIPO.[223] However, this would require some technical patent examination capacity in URSB, which does not appear to be currently available.[224] As already observed in chapter I, a reform of the national intellectual property office, ensuring in-house technical capacities, would be important, also in the context of patent opposition.

Otherwise, the URSB would have no choice but to forward the patent application to ARIPO, without examining the opposition. ARIPO examiners would not be able to take the opposition into account, because under the Harare Protocol, there is no provision allowing third party oppositions.[225] This is a problem similar to the diverging standards of novelty as laid down in the Harare Protocol and the Ugandan Industrial Property Bill, as discussed in chapter I. Even if the URSB forwarded the opposition to the ARIPO examiners, the latter would not be authorized, under the Harare Protocol, to take such third party oppositions into account, unless the protocol were amended to that effect.

Alternatively, the URSB would have to wait for ARIPO to carry out the substantive examination of the patent application and to notify the URSB by sending a copy of its affirmative finding.[226] Before this finding can take effect in Uganda, the URSB would have six months from the date of the ARIPO notification to make a written communication to the latter that the patent in question shall have no effect in the territory of Uganda for the reason that, because of the nature of the invention, a patent cannot be registered or granted or has no effect under Ugandan patent law (section 3(6)(ii) of the Harare Protocol). In most cases, however, this would require the URSB to carry out a substantive examination of the patentability criteria as established under sections 9 and 13 of the bill (see section 28(9) of the bill, dealing with the novelty, inventive step and industrial application requirements as well as the non-patentable inventions clause). As mentioned before, the URSB lacks experience in substantive patent examinations due to the fact that substantive examinations are carried out by ARIPO. Alternatively, the URSB could rely on an international prior art search and an International Preliminary Examination Report conducted by PCT examiners. However, as already mentioned under chapter I, PCT examiners may be unaware of the particularities of national patent law, especially if these relate to specific interpretations that are not laid down in written form.

Thus, the opposition procedure of the Industrial Property Bill (section 28(7)) could best unfold its beneficial effect if the URSB were thoroughly reformed to include some technical capacity, along the lines suggested in chapter I. In addition to this, the Harare Protocol should be amended to enable third party patent oppositions. Considering that next to Uganda, Burundi and the United Republic of Tanzania have provided for patent opposition procedures in their draft patent laws,[227] these governments could seek to promote an agreement with other ARIPO members on such an amendment of the Harare Protocol. Whether this is politically feasible is another question. In any case, this illustrates the need for coordination between national and regional entities, if effective changes are to be made.

5.3. **Patentable subject matter** (Section 8, Industrial Property Bill)

Section 8 of the bill clarifies the meaning of “invention” as the basic object of patentability. The provision leaves open, however, to what extent natural substances may be regarded as inventions or rather as non-patentable discoveries.[228] This question carries 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.[229]

Considering Uganda’s National Drug Policy strategy no. 8 to encourage local pharmaceutical manufacturers to produce essential drugs at competitive prices, and also considering the fact that Uganda’s drug procurement agencies rely mainly on generic products, the definition of “invention” in section 8 of the bill should accommodate the interests of foreign and domestic generic drugs producers. In order to allow, to the greatest possible extent, for the reverse engineering and subsequent production of drugs that are based on natural substances, section 8 of the bill could be amended to exclude from the notion of “invention” substances as they exist in nature or that have been isolated from nature. A similar recommendation was

made in UNCTAD's 2008 comparative study on the EAC partner States' patent laws.[230] An example in this regard may be provided by article 7(b) of Argentina's Patents Act, which excludes from patentability, inter alia, "all biological and genetic material existing in nature or derived therefrom in biological processes associated with animal, plant and human reproduction, including genetic processes applied to the said material that are capable of bringing about the normal, free duplication thereof in the same way as in nature."[231]

On the other hand, to the extent that the biological material has not only been isolated from its natural environment, but purified or structurally modified through human intervention, the resulting product would incorporate some technical changes, which would still qualify as "invention", even if section 8 of the bill were amended as suggested. Finally, the exclusion from the notion of "invention" of isolated natural substances 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 by using a different, non-patented process.

5.4 Patentability of new uses of known substances or processes
(Section 38(1)(c) of the Industrial Property Bill)

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 to treat HIV/AIDS. The question arises to what extent a substance, which 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 no. 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 in chapter I, 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 (for details, see chapter I). 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, including in the area of traditional medicines.

5.5 Patentability of product derivatives

As opposed to the new use issue, the question of patentability of pharmaceutical product derivatives does not concern different uses of the same substance, but different forms of that substance. While the new use issue relates to several uses of identical chemical entities, the present section discusses products that are of a slightly different chemical structure than the originally patented product. These slight variations in structure may have more or less important effects on the medical efficacy of the respective drug. Pharmaceutical companies may be interested to see their own product derivatives protected by a patent.

On the other hand, the patenting of product derivatives may complicate generic production. 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 does not expressly refer to product derivatives. Considering the practical importance of this issue,[232] it seems appropriate for policymakers to decide whether product derivatives merit patent protection. Whether this is reflected directly in the patent law or rather in a set of patentability guidelines is a matter of domestic policy preference. Addressing this issue in guidelines may have the advantage of increased flexibility. In any case, product derivatives arguably deserve patent protection where they significantly increase the efficacy of the medical product, thus contributing important benefits to society. In this respect, foreign approaches, such as those in India and the United States, may provide some important guidance, as discussed in UNCTAD's 2008 comparative study on the EAC partner States' patent laws.[233]

Despite some methodological differences in approach, both the Indian and the United States legislation treat structural similarities occurring in product derivatives as undeserving of product patent protection, unless the structural modifications result in new, improved or unexpected properties (United States law[234]) or in significantly enhanced efficacy (Indian law[235]). While the Indian law addresses the issue in the context of the definition of "invention" and also under the novelty requirement, United States case law regards product derivatives as an element of the inventive step test. Any of these requirements may be used to filter out insignificant and trivial derivatives of known products on a case-by-case approach.

To this end, the domestic patent law or regulations (where available) could provide that structural similarities create a presumption of lack of invention, novelty or inventive step (in the latter case, taking into account the typical level of creativity and insight of the person with ordinary skills in the art). The burden of proof would then lie on the patent applicant to demonstrate significantly superior properties with regard to efficacy of the variant.

This said, it should be acknowledged that for developing country patent examiners, the requirement of superior efficacy might be difficult to assess. The authorities may wish to invoke high-level expert opinion, or even establish a board of distinguished external advisers. Reliance on PCT examiners (in the context of an International Preliminary Examination Report) has been questioned lately on grounds of falling quality[236] and should not therefore substitute for appropriate action by national authorities. In order to assist PCT examiners, a clear reference to derivatives should be included in the patent law, along the lines suggested in the preceding paragraph. Moreover, care must be taken to maintain strict standards consistently over time, lest inconsistent decisions lead to premature lowering of standards.

In case the government agrees with the above approach, the question arises as to what extent those product derivatives that do not meet the definition of "invention" (or, alternatively,

fail the novelty or inventive step tests) should nevertheless be granted some form of protection. The situation is comparable to the new use issue. Even where the development of derivatives does not meet strict patentability requirements, it may still take a certain effort. Such incremental innovation may be useful to society, and local producers are more likely to engage in those activities than in breakthrough inventions. Utility model protection could provide an answer in this respect, under a 10-year term of exclusivity. Alternatively, a non-exclusive use and pay regime, following a brief period of exclusivity, as suggested in the new use context, could also provide an appropriate way of incentivizing investments in incremental innovation, without blocking access by competitors to the modified substance.

5.6 **Regulatory review exception** (Section 44(b) of the Industrial Property Bill)

A patent authorizes the right owner to exclude others from, inter alia, using the protected product or process, but not to put the patented product on the market. With respect to pharmaceutical products, such authorization may often be obtained from a specialized government body, hereinafter referred to as the DRA (drug regulatory authority). Generic producers, in order to obtain marketing approval, often depend on the use[237] of essentially the same substance or active ingredients as that used in a patented drug, for which the originator has already received marketing approval, based on clinical trial data.

If the patent holder could use his exclusive right to prevent generic producers from using the patented substance in these ways in order to obtain marketing approval, a generic producer could only prepare to submit his request for marketing approval after the patent has expired. Considering the time required for the approval process, marketing of the generic drug would thereby be delayed to well after the expiry of the patent, thus extending, de facto, the exclusive position of the patented drug on the market.[238] Thus, the regulatory approval exception is one important pro-competitive tool commonly used by WTO members.[239]

The Industrial Property Bill (section 44(b)) is not limited to marketing approval applications in Uganda, but provides that the exception may also be invoked against the patent holder in Uganda to justify uses of the patented substance that are reasonably related to the development and submission of information to foreign drug regulatory authorities. This wide interpretation of the exception is in line with the decision by the WTO panel in the *Canada–Pharmaceuticals* case.[240]

In addition, the use in section 44(b) of the terms “reasonably related to” the development and submission of information required for marketing approvals may be understood as covering not only clinical, but also pre-clinical trials, as previously done under Canadian and United States legislation on the same issue. This broad interpretation has been considered legitimate by the Supreme Court of the United States, in the 2005 decision in *Merck v. Integra Lifesciences*.[241] In this decision, the Supreme Court interpreted the United States regulatory review exception as authorizing the use of patented inventions for the purpose of conducting research with respect to drugs as to which there is some reasonable prospect that an application for marketing approval may be submitted, regardless of whether an application is, in fact, eventually submitted or successful.[242]

This option has important implications for competitors of a company holding a pharmaceutical patent. These competitors may depend on the availability of patented materials not only for the purpose of the actual submission of the approval request, but also during the early phases of their own pharmaceutical R&D, to the extent this is necessary for the development of generic drugs. This may be of particular importance where generic producers or other competitors seek to engage in follow-on innovation on the patented substance, for example by identifying the potential of a patented compound for new medical indications.[243] In this context, reference is made to the discussion on the patentability of new uses (see 5.4 above). Skilled generic competitors would seem to be more inclined to use the

regulatory review exception to engage in follow-on R&D where they are granted some incentive. As discussed, a use and pay regime for incremental innovations, in the form of new uses or minor product derivations, may provide an appropriate tool in this regard, while not blocking access of competitors, as under new use patents.

5.7 Parallel imports

> 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 her consent. (emphasis added) (section 43(2) of the Industrial Property Bill)

Parallel importation constitutes another important mechanism that could encourage competition in the market and eventually lower the prices for medicaments by taking advantage of the price difference between countries. Low-priced products are imported in parallel to the official channels of distribution established by the IPR holder (in this context the holder of a pharmaceutical patent). In addition, parallel imports may provide an important source of affordable pharmaceutical substances needed by generic manufacturers for their own production. It is important to note that parallel imports are not counterfeits; they are original products of the patent holder sold by him or an authorized person on a given market, and purchased and subsequently resold by a third party.

The language employed in the quoted section 43(2) of the Industrial Property Bill is rather ambiguous. The provision seems to address two different situations: first, the marketing of a patented article, either in Uganda or abroad; second, the importation into Uganda of a patented article. The marketing or first sale of a patented product by the patent holder or with his consent is the action that triggers the exhaustion of the exclusive distribution rights (i.e. to use, offer for sale, sell or import the protected article). The provision, by referring to the marketing in Uganda or abroad, indicates a regime of international patent exhaustion, thus legitimizing parallel imports.

The second situation addressed by the bill, the importation into Uganda of an article that is protected under a Ugandan patent, is not directly relevant to the issue of exhaustion. A patent right cannot be exhausted through the act of importation; what matters is whether such importation at the same time constitutes the first sale of the product. The above provision seems to have been drafted specifically to cover those cases where the first marketing of the product is done through importation, but these cases are already covered under the first scenario, i.e. the marketing of the product in Uganda. Whether such marketing is preceded by the importation of the product, or whether the product has been produced in Uganda, has no relevance in this context.

Therefore, the reference in section 43(2) of the Industrial Property Bill to importations into Uganda should be deleted, as it appears rather superfluous.

Section 43(2) of the Industrial Property Bill applies to products from all sectors of technology, including finished pharmaceuticals as well as separate pharmaceutical ingredients such as APIs. The latter are increasingly patent-protected in those countries from which they are sourced, for example in India after the introduction in 2005 of pharmaceutical product patent protection.

It should be noted that due to the 2016 transition period as implemented under section 8(3)(f) of the Industrial Property Bill, section 43(2) will not have any immediate impact in the area of pharmaceuticals, because pharmaceutical product patents cannot be enforced in any case. This being said, however, the authors of this report consider an international patent exhaustion regime to be beneficial for Uganda's public health policies, for the following

reasons. After the transition period, parallel importation may enable the continued supply of drug ingredients that local manufacturers cannot make themselves, such as APIs. At the same time, public procurement could also purchase and import finished pharmaceutical products from abroad, in case these are more affordable than locally produced medicines.

While for the time being, Uganda's public health system does not rely on parallel imports of patented products but on foreign generic drugs,[244] the increased number of pharmaceutical patents in countries where important shares of Uganda's imported generics are produced will limit the amount of modern drugs that may still be sourced as generics. Especially after 2016, the possibility of parallel importation may become an important option for the country's public health and procurement system. Parallel imports would thereby enter into competition with local products. It is for this reason that local industry representatives have objected to parallel imports of products that can also be manufactured locally.[245] This illustrates that what is desirable from an access to medicines perspective may at the same time not always be desirable from an industrial development standpoint.

On the other hand, even local industry will be able to benefit from parallel imports after 2016, to the extent it cannot manufacture its own APIs, which are the core component of every drug, and which will soon be less available in generic form. While the local industry's concern about competing finished products from abroad is acknowledged, it appears difficult to fully accommodate their wishes. For instance, it would not be feasible to admit parallel imports of patented APIs, but reject parallel imports of patented finished pharmaceutical products. Patent owners in other areas of technology could allege discriminatory treatment of their products (article 27.1, TRIPS Agreement), which could be imported freely in finished form, against their will. While differential treatment of different areas of technology for bona fide purposes would arguably not constitute discrimination in that sense, it is questionable whether the exclusion of cheaper foreign finished pharmaceutical products could qualify as being bona fide. After all, conferring an economic advantage on local industry seems hard to reconcile with bona fide purposes to the extent that the local products are actually more expensive than the excluded foreign drugs.

As mentioned above, it also appears difficult to prevent the importation of foreign, finished pharmaceutical products through tools not related to intellectual property, such as tariffs, since the EAC's Common External Tariff on these products has recently been reduced to zero.

Finally, if the authorization of parallel imports of patented products in the Industrial Property Bill is to produce a real impact, it is important to ensure that the patent holder cannot oppose the importation of his products on the basis of other intellectual property laws, such as trademark and copyright law. Patented pharmaceutical products are usually marketed under protected brand names, and the pharmaceutical description on the drug package may be copyright protected.[246] In case parallel imports of trademarked or copyrighted goods are not authorized, imported drugs have to be seized by customs authorities at the border, despite the authorization under domestic law to parallel import patented products.

Section 32(1)(a) of Uganda's Copyright and Neighbouring Rights Act, 2006, states that "infringement of copyright or neighbouring rights occurs where, without a valid … authorization … a person deals with any work or performance contrary to the permitted free use and in particular where the person does or causes or permits another person to … *import into Uganda* otherwise than for his or her own private use". (emphasis added)

This provision qualifies any imports into Uganda as copyright infringements, without specifying that no infringement will take place if the copyrighted work before being imported into Uganda has already been marketed in a foreign country by the copyright holder or with his consent. Without such a specification, the above provision must be interpreted as

implying a rule of national copyright exhaustion, i.e. where the right to distribute the copyrighted work is only exhausted upon the first sale of the protected item on the national market of Uganda. To the extent that imports of packages and bottles of medicines display copyrighted text (i.e. the pharmaceutical description of the product, if copyrightable under domestic law), they could constitute copyright infringement under Ugandan copyright law and would have to be stopped by customs authorities. This would seriously limit the value of the authorization of parallel imports of patented products.

As to trademarks, neither Uganda's Trademarks Act of 1953 (chapter 217, Laws of Uganda) nor ARIPO's Banjul Protocol on Marks, to which Uganda is a party, contain any reference to the issue of parallel imports/trademarks exhaustion.

In the current situation, the best way to avoid findings of trademark (and possibly copyright) infringements would be for the importer to repackage the pharmaceutical products, applying his own trademark and possibly drug descriptions. It is obvious that such an exercise will be costly and cause an increase in price of the drugs as charged to consumers or procurement agencies, thus defeating the very purpose of parallel imports.

5.8 **Compulsory licences** (Sections 58–64 of the Industrial Property Bill)

Compulsory licences can be an important instrument both to promote the wider availability of medicines at affordable prices and to promote the establishment of a generic pharmaceutical industry. To the extent that a country seeks to attract investment from foreign, patent-owning companies, including R&D-based pharmaceutical companies, this instrument should be used with care. In the context of the WTO, a recent amendment to the TRIPS Agreement on compulsory licences (i.e. the new draft article 31*bis*) facilitates the task of local pharmaceutical producers in LDC-dominated regional trade agreements (such as the EAC) who seek to produce certain drugs for the entire region.[247]

The Industrial Property Bill (sections 58–66) contains a number of detailed rules on the granting and exercise of compulsory licences and government use licences. These rules appear to implement, to a large extent, the flexibilities provided under the TRIPS Agreement. The following paragraphs briefly describe where further adjustments or clarifications could be made, in the interest of promoting access to medicines, but also in order to meet the TRIPS minimum standards after the expiry of the 2013 transition period. A number of these points were also raised in UNCTAD's 2008 comparative study on the EAC partner States' patent laws.[248]

- Section 66(3) of the bill provides that in case of government use licences, a ministerial order authorizing a compulsory licence "shall not require the payment of compensation to the owner of the patent or licence holder or any other party interested". This seems to be in disregard of the requirement in article 31(h) of the TRIPS Agreement to provide for "adequate" remuneration. The TRIPS Agreement authorizes that anti-competitive behaviour "may be taken into account in determining the amount of remuneration in such cases". However, the agreement contains no authorization to generally exclude remuneration in cases of government use. The government should consider bringing section 66(4) of the bill in line with the minimum standards under article 31(h) of the TRIPS Agreement notwithstanding the fact that Uganda is not bound by the agreement at present;

- Neither the provisions on compulsory licences nor the rules on government use licences provide the patent holder with the possibility to invoke an independent review of the decision to grant a compulsory/government use licence.[249] The TRIPS Agreement in article 31(i) requires members to establish such a review through an independent body that is not subject to any control by the issuing agency. In case of a

compulsory licence granted by a court, this decision should be subject to appeal to a court of a higher instance. In case of government use licences, the granting decision should be subject to review either by a more senior government entity or by an independent court. If the government wishes to do so, it is authorized under article 44(2) of the TRIPS Agreement to exclude injunctive relief as a remedy available under independent review. This means that, until a final decision on the legality of the compulsory or government use licence is rendered, the alleged infringer may continue using the patented substance against the payment of royalties to the patent holder.[250] This would have no effect on the availability of injunctive relief as a general remedy in patent infringement cases (section 93 of the Industrial Property Bill), which have to be distinguished from the particular case of alleged infringement through compulsory licensing;

- Article 31(j) of the TRIPS Agreement provides for a comparable obligation to make available an independent review of the decision fixing the amount of remuneration to be paid to the patent holder. The Industrial Property Bill contains no such possibility for the patent holder, neither in case of a compulsory licence granted by a court, nor in case of a government use licence. Under the latter scenario, section 66(4) even authorizes the government to exclude payment of remuneration in the first place (see above).

While the previous issues indicate inconsistencies in the Industrial Property Bill with certain TRIPS minimum standards, the following provisions in the same bill should be noted as not fully taking advantage of the flexibilities that Uganda is granted under the provisions on compulsory licensing of the TRIPS Agreement:

- Section 60(1)(a) of the Industrial Property Bill does not specify the period to be respected when seeking a voluntary licence from the patent holder. The TRIPS Agreement leaves members free to determine the appropriate time frame. It may be helpful to do so in a set of administrative regulations on the implementation of the Industrial Property Law. Burundi's Draft Patents Act of 2007 provides some interesting guidance to this effect, by suggesting a maximum negotiation period of six months.[251] However, as in cases where the production of life-saving drugs is urgently needed, six months can appear too long of a period, and an exception could be stated providing for a maximum period of 45 days only, in line with the provision in the United Republic of Tanzania's March 2008 Draft Bill for an Act on Industrial Property Rights for Zanzibar.[252] A differential treatment of different areas of technology for public health (i.e. bona fide) reasons would arguably not constitute "discrimination" within the meaning of article 27.1, TRIPS Agreement.[253] In this context, it should be noted that for generic producers seeking economies of scale, harmonized rules on negotiation timelines among EAC partner States would considerably facilitate EAC-wide production under a compulsory licence;

- Section 44(e) makes use of the draft article 31*bis* TRIPS system as an exporting country, but does not specify that when using the 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.[254] Section 61(2)(e) of the bill, which addresses the issue of remuneration, could be amended to this effect;

- Section 61(1) of the Industrial Property Bill provides that compulsory licences other than government use licences have to be granted by the courts, as opposed to through administrative procedures (i.e. the minister or other government agency). The TRIPS Agreement does not require members to make the grant of a compulsory licence dependent on the completion of a lengthy judicial procedure. The Industrial

Property Bill provides for the granting of compulsory licensing by the minister, but limits this to cases where the government itself exploits the patented invention, or a third party on behalf of the government (government use). This does not seem to cover, however, cases where a private party, such as a generic producer, is authorized to exploit the invention on his own account, in order to address a public health-related problem;

- Finally, section 102(8) addresses the particular situation of LDC-dominated trade agreements under the Decision of the World Trade Organization General Council of 30 August 2003, which is supposed to facilitate the export to needy countries of pharmaceutical products produced under a compulsory licence. As an exception to the general rule, paragraph 6 of that decision authorizes re-exports that are destined to countries that are members of a regional trade agreement composed of at least 50 per cent LDC members, provided the importing developing country or LDC members share the health problem in question. In that case, the Ugandan (re-)exporter would not need to notify the WTO, nor would he have to meet any of the requirements applying to exporting countries. While section 102(8) of the Industrial Property Bill in this respect refers to the members of the Common Market for Eastern and Southern Africa (COMESA), it omits any reference to the EAC partner States. This is an important shortcoming, because after 2016, Ugandan suppliers and producers will not be able to re-export drugs produced or imported under compulsory licence to the United Republic of Tanzania, which is a partner State of the EAC, but not a member of COMESA. In addition, this approach is not in line with the decision by the EAC to facilitate trade among EAC partner States by eliminating EAC internal tariffs.

5.9 Protection of pharmaceutical test data (Section 35 of the National Drug Policy and Authority Act; Guidelines on Registration of Pharmaceutical Drugs for Human Use in Uganda (revised August 2001); section 11(2) of the Trade Secrets Protection Act, 2009)

Article 39.3 of the TRIPS Agreement broadly obligates members to provide protection for undisclosed pharmaceutical test data against "unfair commercial use". Most of the WTO's developed members have chosen to implement this obligation through the granting of exclusive rights in pharmaceutical test data. This means that in the context of approving generic copies of originator drugs, the DRA may not, for a certain period, rely on the test data provided by the innovator company. Rather than only proving bioequivalence,[255] a generic competitor would then have to submit an entire new file of data proving the safety and efficacy of his generic copy. In addition, some members, especially where bound by certain bilateral or regional free trade agreements, link the independent areas of drug regulation and patent law, preventing the DRA from granting marketing authorization for a generic product if that product is still protected under a domestic patent.

The TRIPS Agreement, however, does not obligate members to follow these approaches. Exclusive rights in test data and patent linkage are likely to delay the market entry of generic competitors upon expiry of the patent term. A country that for its public health policies mainly relies on generic products is free under the TRIPS Agreement to protect test data against use in unfair commercial practices, but to enable its DRA to rely on the data originator's data for the approval of generic competing products. Generic producers in that case only have to prove bioequivalence of their products. A DRA cannot necessarily be expected to be aware of the patent status of a given drug. The enforcement of existing pharmaceutical products should therefore not be up to the DRA, but to the patent holder. In case a generic competitor, after receiving marketing approval, ignores the patent and proceeds with the marketing of the product, the patent holder is free to initiate a patent infringement suit in a domestic court. This may at the same time provide the generic producer with an opportunity to challenge existing patents of poor quality, i.e. patents that should never have been granted in the first

place. In OECD countries, serious concern has recently been expressed, for example by the European Commission and the United States Federal Trade Commission, on the significant numbers of "bad" patents in the European Union (EU) countries and the United States.[256]

In Uganda, the Trade Secrets Protection Act, 2009 (see chapter I) implements the obligation under article 39 of the TRIPS Agreement to provide for protection of undisclosed information. Section 11(2) of this Act provides protection against unfair commercial use of pharmaceutical or agricultural test data submitted to a government agency for marketing approval purposes. By referring to "unfair commercial use", this provision reproduces the language used in article 39.3 of the TRIPS Agreement.

While the Trade Secrets Protection Act contains no further explanation of how to interpret these terms, guidance may be drawn from existing practice in drug regulation:
section 35 of the National Drug Policy and Authority Act in broad terms authorizes the NDA to examine the safety, efficacy and quality of drugs and establish a system for the approval of drugs that are not included on the country's essential medicines list. According to the Guidelines on Registration of Pharmaceutical Drugs for Human Use in Uganda (section 2: applicant), eligible applicants for drug registration are the patent holder, the manufacturer or other parties authorized by the patent holder. The reference to "the manufacturer" has been interpreted by senior NDA staff as authorizing any manufacturer to submit an application for drug registration, irrespective of the patent status of the substance at issue.[257] The NDA has made clear, in this respect, that "it will register any drug with proof of safety, efficacy and quality and shall not be involved in enforcement of patents".[258]

This means that as far as pharmaceutical test data are concerned, the protection against "unfair commercial use" in the Trade Secrets Protection Act does not establish any exclusive rights in the data, but leaves the regulatory authority the freedom to rely, in the course of approving generics, on the data previously submitted by the originator company. This appears an appropriate approach, considering that the TRIPS Agreement does not require members to obligate their regulatory authorities to assist in the enforcement of patents, but is based on the premise that enforcement of a patent, which is a private right, is first and foremost the patent owner's responsibility.

5.10 Enforcement of IPRs (Counterfeit Goods Bill, 2009)

This bill in part I, section 2, defines "counterfeiting" as follows:

> "Counterfeiting" means without the authority of the owner of any intellectual property right subsisting in Uganda in respect of protected goods –
>
> (a) The manufacturing, producing, packaging, repackaging, labelling or making, whether in Uganda or outside Uganda, of any goods by which those protected goods are imitated in such manner and to such a degree that those other goods are identical to or substantially similar to protected goods;
>
> …
>
> (c) In the case of medicines, *includes* the deliberate and fraudulent mislabelling of medicines with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging. (emphasis added)

Remedies in cases of dealing with counterfeit goods include criminal sanctions, i.e. fines of at least five times the value of the market price of the genuine goods, imprisonment not less than five years (seven years in case of production of counterfeit goods), or both.[259] As opposed to the minimum requirements under article 61, TRIPS Agreement, the bill thus

applies criminal sanctions not only to certain cases of trademark and copyright infringement, but to the breach of any intellectual property right, which includes (pharmaceutical) patents. 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, including an application of the complex doctrine of equivalents.[260] Under the threat of fines and imprisonment, generic pharmaceutical producers may be extremely hesitant to engage in the production of certain substances. Even where innocent, litigation may be time consuming and costly, and pending criminal procedures against a company may be considered as detrimental to its reputation in the market. It may be for these reasons that in major OECD countries, such as the United States, patent infringements are not sanctioned by criminal law remedies.[261] In addition, the Counterfeit Goods Bill entrusts the Uganda National Bureau of Standards with the administration of the bill.[262] While the bureau may have the capacity to identify counterfeit trademarked goods or pirated copyrighted goods, they are not in a position to examine the existence, scope and validity of an alleged patent.

For these reasons, 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.

In the case of unauthorized production, use or sale of patented medicines (in particular as of 2016) by generic producers, 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, i.e. to prevent the entry of infringing products into the channels of commerce (article 44.1, TRIPS Agreement);
- Damages for wilful infringements to compensate for the injury suffered by the infringement (article 45);
- Possibly the destruction of infringing goods or their disposal outside the channels of commerce (article 46);
- Provisional measures to prevent IPR infringements from occurring, or to preserve relevant evidence in respect of alleged infringements (article 50).

In case the above amendment is not politically feasible, attention should be paid to the separate subparagraph on medicines, as quoted above, in the definition of “counterfeiting”. This separate subparagraph (c) (which should be (d); there is an apparent numerical error) on medicines was not included in the 2008 version of the bill, but added in 2009. It seems to address concerns voiced by generic producers about their manufacturing activities being qualified as counterfeiting and thus subject to the criminal law remedies provided under section 16 of the Counterfeit Goods Bill.[263] Similar concerns were raised with respect to Kenya’s Anti-Counterfeiting Bill,[264] which in its final version also includes a specific definition of “counterfeiting” in the medicines context, comparable to paragraph (c) as quoted above.[265]

As to Uganda’s Counterfeit Goods Bill, the new subparagraph (c) as quoted above now seeks to clarify that in the case of medicines, only those activities shall be regarded as “counterfeiting” that relate to the deliberate and fraudulent mislabelling of pharmaceutical products. This is similar to a definition developed by the WHO on counterfeit drugs.[266] Applying criminal law sanctions in the case of deliberate and fraudulent trademark counterfeiting is in line with TRIPS Agreement minimum standards (article 61).

This being said, it would seem appropriate to make a few amendments to the existing language of subparagraph (c), in order to avoid misunderstandings on its scope. First, the

current version states that counterfeiting, in the case of medicines, "includes" the deliberate and fraudulent mislabelling without the authority of the intellectual property owner. This could be misunderstood as implying that paragraph (a) regarding manufacturing activities still applies in addition to paragraph (c), thus qualifying generic producers' activities as counterfeiting. From a systematic interpretation, it should be clear that the intention of inserting the separate subparagraph on medicines was to create a *lex specialis* that excludes the application of all other subparagraphs in the case of medicines, including subparagraph (a). Such an interpretation could be facilitated by deleting the term "includes" in subparagraph (c) as quoted above. The comparable Kenyan provision does not refer to this term either.[267] In addition, a final sentence could be added at the end of that subparagraph, stating that in the case of medicines, the other subparagraphs do not apply.

Second, subparagraph (c) in its current version broadly refers to "medicines". The same paragraph 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 APIs 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.

Third, section 3 should be amended, stating that in the case of medicines counterfeiting, the leading agency to administer the Act is the NDA.

6. Summing up: Main recommendations

6.1 Local industry promotion and trade policy
Recommendation no. 12: Consider preferential treatment of local producers

- In harmony with the objectives and strategies in the National Drug Policy, government procurement agencies such as the MoH and the JCRC should consider providing preferential treatment to local producers in medicines procurement activities. However, such preferential treatment only makes sense to the extent that domestic manufacturers are capable of producing quality products that meet WHO pre-qualification requirements, i.e. quality, safety and efficacy of the products, as well as compliance of the manufacturing site with GMP, or at least domestic quality and GMP standards that guarantee safe and efficacious medicines. In addition, production has to be economically viable, which means overcoming the difficulties described above in terms of uncompetitive prices and unqualified local personnel;
- Given that local producers are still at early stages of development and technological capacity, it is as yet difficult to assess this manufacturer's potential viability and performance in terms of quality, low cost production. Therefore, the government may wish to first collect verifiable evidence in this respect, before accommodating local industry preferences for higher import tariffs on finished pharmaceuticals. Any modifications of tariffs (such as the EAC Common External Tariff) in this regard may have negative impacts on the availability in Uganda and the EAC of foreign-sourced, high quality pharmaceutical products.

6.2 Drug regulation policy and law
Recommendation no. 13: Ensure independent funding of the Ugandan National Drug Authority

The above recommendation on the promotion of local pharmaceutical producers is contingent on the establishment of a reliable institutional infrastructure for the regulation and enforcement of drug quality standards, following good governance principles.

- The WHO has considered drug registration procedures before the Ugandan NDA as speedy, the technical staff as sufficiently skilled and less subject to personnel fluctuations than in comparable developing countries;
- Nevertheless, the WHO has considered the NDA as being underfunded, despite very encouraging developments over the past years concerning the amounts of funds received by the NDA as well as important increases of internally generated revenue. In order to ensure the continuation of these encouraging developments, it seems essential for the NDA to continue receiving the bulk of its revenue from services fees, making it independent from foreign donor or government funding. An important element in these efforts is continuous consultation with stakeholders to ensure fees, while supporting the NDA's activities, do not overburden domestic companies.

6.3 Industrial property policy and law

Taking account of the cross-cutting nature of public health policies, the impact of any changes to the domestic intellectual property system on access to medicines can be improved if addressed in tandem with the recommendations in the areas of industry promotion and drug regulation. Any changes in the country's intellectual property policy and law should be guided by Uganda's dependence on generic products.

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.

Recommendation no. 15: Enhance the effectiveness of third party patent oppositions

- The opposition procedure in section 28(7) of 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 the URSB, enabling it to benefit from technical know-how available in other institutions such as the UNCST, the UIRI and others;
- In addition, the Harare Protocol should be amended to take account of third party oppositions. The government should consult with the governments of other EAC partner States that follow comparable approaches (especially Burundi and the United Republic of Tanzania) as to what extent an amendment of the Harare Protocol seems feasible.

Recommendation no. 16: Exclude natural substances as such from patentability

- In order to allow, to the greatest possible extent, for the reverse engineering and subsequent production of drugs that are based on natural substances, section 8 of 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. 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 by using a different, unpatented process.

Recommendation no. 17: Exempt applications of traditional knowledge and genetic resources from new use patents and introduce a use and pay regime

- The Industrial Property Bill (section 38(1)(c)) provides for the patenting of new uses of known products. The government should consider excluding applications of traditional knowledge and genetic resources from new use patents. As suggested under chapter I (Recommendation no. 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 any improvement uses of their know-how and biodiversity. This may improve domestic capacities in agricultural technologies, agribusiness and pharmaceuticals, which are among the government's priority areas for attracting investment.

Recommendation no. 18: Provide for rules on the patenting of pharmaceutical product derivatives

- As regards the patenting of pharmaceutical product derivatives, 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 (in the latter case, taking into account the typical level of creativity and insight of the person with ordinary skills in the art). The burden of proof would then lie on the patent applicant to demonstrate significantly superior properties with regard to efficacy of the variant.
    - Those product derivatives that do not meet the above criteria 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 (see Recommendation no. 8).

Recommendation no. 19: Provide coherence among domestic exhaustion regimes

- As regards parallel importations, the reference to "importation into Uganda" of patented products (section 43(2), Industrial Property Bill) should be deleted. 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.
    - Considering Uganda's increasing dependence on the parallel importation of patented foreign substances (including APIs for successful local producers), the government's choice of legitimizing parallel imports seems appropriate. The same approach should be chosen under Ugandan trademark and copyright law. This requires an amendment of section 32(1)(a) of the Copyright and Neighbouring Rights Act 2006 (see also Recommendation no. 30).

Recommendation no. 20: Make compulsory licensing rules TRIPS-compliant

- The bill (section 66(3)) 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 licence. However, this does not apply to the case of pharmaceutical products that should be brought in conformity with TRIPS by 2016;
- By 1 July 2013, any decision to grant a compulsory or government use licence 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. In particular government use licences may be excluded from injunctive relief, provided the alleged infringer pays royalties to the patentee for continued use of the protected substance until a final judgment on the legality of the government use licence is reached. In addition, the patentee should have the right to claim compensation from the licensee if after judicial review the compulsory licence turns out to have been wrongly granted. Independent review authorities may be a (higher instance) court or a more senior government agency;
- 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 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. Independent review authorities may be a (higher instance) court or a more senior government agency.

Recommendation no. 21: Make full use of TRIPS flexibilities in compulsory licensing

- As regards negotiations for a voluntary licence with the right holder, the Industrial Property Bill (section 60(1)(a)) could be amended to include a reference to a maximum period of negotiations with the right holder before granting a compulsory licence. 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 2007 Draft Patents Act), 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 March 2008 Draft Bill for an Act on Industrial Property Rights for Zanzibar). For generic producers seeking economies of scale, harmonized rules on negotiation timelines among EAC partner States would considerably facilitate EAC-wide production under a compulsory licence;
- On the remuneration of the patent holder under a compulsory licence, section 61(2)(e) of the Industrial Property Bill should be amended to provide that when using the draft article 31*bis* 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(1) of the Industrial Property Bill should be amended to include the possibility of administrative (as opposed to judicial) grants of compulsory licences for private third parties acting on their own behalf and account. The ministry primarily involved should be authorized to issue the compulsory licence. In the area of pharmaceuticals, this should be the Ministry of Health;
- On re-exportations of pharmaceuticals produced under compulsory licence under the WTO 30 August 2003 Waiver Decision, section 102(8) should not only refer to COMESA, 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.

Recommendation no. 22: The protection of pharmaceutical test data

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

Recommendation no. 23: Amend the Counterfeit Goods Bill

- 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;
- 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 and 50, TRIPS Agreement);
- In case the above amendment is not politically feasible, the definition of "counterfeiting" in the context of medicines in section 2, paragraph (c) of the bill should be amended
    - Delete the term "includes". This would clarify that the term "counterfeiting" does not include the unauthorized manufacturing, producing, packaging, repackaging, labelling or making of pharmaceutical products, but is limited to the deliberate and fraudulent mislabelling of medicines;

- In addition, a sentence could be added, stating that in the case of medicines, the other subparagraphs do not apply;
- The 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 APIs 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 3 of the bill should be amended, stating that in the case of medicines counterfeiting, the leading agency to administer the Act is the NDA.

Notes

138 See UNDP (2008).

139 See Uganda AIDS Commission (UAC) (2007). *Moving Toward Universal Access: National HIV and AIDS Strategic Plan 2007200/8– 2011/2012*. Kampala.

140 Ibid.: i.

141 Ibid.: vii.

142 See HEPS-Uganda (2008a). HIVOS, HEPS-Uganda in partnership against HIV/AIDS epidemic. *Medicines Acces Digest: A Quarterly Newsletter of HEPS Uganda*. 4 (1).

143 Interview with Dr. Cissy Kityo, Deputy Director Research, JCRC, 15 May 2008.

144 UAC (2007): viii, referring to 2005.

145 See WHO (2008). Uganda edges closer to AIDS treatment for all. *WHO Bulletin.* 86 (6). (http://www.who.int/bulletin/volumes/86/6/08-020608/en/index.html). Note that the WHO 2007 figure of those in need of ARVs is much higher than the estimates advanced by MoH for 2006 (i.e. 312,000 (WHO) as compared to 234,500 (MoH)).

146 WHO (2009). Country profile Uganda. http://www.who.int/countries/uga/en/ and more specifically http://rbm.who.int/wmr2005/profiles/uganda.pdf.

147 WHO (2009).

148 See http://www.who.int/csr/don/archive/country/uga/en/. On the first reported Ebola outbreaks, see WHO (2000). Press release: Ebola haemorrhagic fever in Uganda. October. (http://www.who.int/csr/don/2000_10_16/en/index.html).

149 Interview with Martin Olowo Oteba, Ministry of Health, 15 May 2008.

150 See, e.g., Straus J (2007). The impact of the new world order on economic development: the role of the intellectual property rights system. *European Review*. 15 (1), referring also to other sectors of industry.

151 On the insufficiency of current efforts to develop medicines to treat diseases predominantly affecting developing countries, see World Health Assembly resolution 61.21 of 24 May 2008, annex on a "Global strategy on public health, innovation and intellectual property", paragraphs 3 and 4.

152 See, e.g., Correa C (2005). Can the TRIPS Agreement foster technology transfer to developing countries? In: Maskus KE and Reichman JH, eds. *International Public Goods and Transfer of Technology under A Globalized Intellectual Property Regime*. Cambridge, Cambridge University Press: 227, 229–232; Reichman JH and Cooper Dreyfuss R (2007). Harmonization without consensus: critical reflections on drafting a substantive patent law treaty. *Duke Law Journal*. 85 et seq.

153 See Commission on Intellectual Property Rights (2002). *Integrating Intellectual Property Rights and Development Policy*. London: 36; and United Kingdom Department for International Development (2005). Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry: A United Kingdom Government policy paper. 20. The view that patents affect drugs prices is not uncontroversial. For the opposite opinion, see Jones T. Public health, innovation and intellectual property rights. In: *Report of the World Health Organization's Commission on Intellectual Property Rights, Innovation and Public Health*. 225, referring to non-IPR-related obstacles. See also Noehrenberg E (2006). The realities of TRIPS, patents and access to medicines in developing countries. In: Pugatch MP, ed. *The Intellectual Property Debate. Perspectives from Law, Economics and Political Economy*. Cheltenham/Northampton: 170–186, arguing that patents confer much less pricing power than usually thought.

154 WTO (2001). Declaration on the TRIPS Agreement and public health. WT/MIN(01)/DEC/W/2. Geneva. 14 November.

155 Unless another extension of the transition period is requested at the WTO's Council for TRIPS. According to article 66.1 of the TRIPS Agreement, LDCs have the right to request extensions of the LDC transition period. While this has been done in the past, article 66.1 does not limit LDCs' possibility to renew such requests.

156 MoH (2002). *Uganda National Drug Policy.* Kampala: 1.

157 See http://www.health.go.ug/.

158 See http://www.jcrc.co.ug/AboutUs.htm.

159 See http://www.aidsuganda.org/.

160 Ibid.
161 See MoH (1999). *National Health Policy*. Kampala: 6.
162 See UAC. National policies and priorities. http://www.aidsuganda.org/policies.htm. UAC stresses current efforts to also consider the impact of HIV/AIDS in the implementation of the other four pillars, i.e. economic management; enhancing production, competitiveness and incomes; security, conflict resolution and disaster management; and good governance.
163 See WHO (2008).
164 See MoH (2002): 7–8.
165 See ibid.: 9.
166 See ibid: 21.
167 Ibid.
168 M. Oteba refers to an average of 70 per cent of the total funding available for the public procurement of drugs and, in some areas such as anti-malarials, even up to 100 per cent, the funding for which is provided by the Global Fund to Fight AIDS, Tuberculosis and Malaria. The WHO refers to Uganda's ARV programme as being 95 per cent donor-funded, see WHO (2008). For an example of the funds provided during 2003–2005 by the World Bank (MAP Project), the Global Fund and the United States President's Emergency Plan for AIDS Relief (PEPFAR), see HEPS-Uganda (2006). Funding the promise: monitoring Uganda's health sector financing from an HIV/AIDS perspective, final report January 2006. Kampala: 13–15.
169 Based on the USH–USD exchange rate as of 9 March 2009.
170 Interview with M. Oteba.
171 See http://www.who.int/bulletin/volumes/86/6/08-020608/en/index.html (citing Ugandan officials as referring to costs between only $2 and $9 per patient per month).
172 Interview with George Baguma, 10 November 2009.
173 Stakeholder discussion on 26 June 2009.
174 See HEPS-Uganda (2007). Missing the target no. 4: Uganda chapter. 17, also referring to other research providers.
175 Interview with C. Ibingira.
176 Ibid.
177 Interview with Elizabeth Ongom, Operations Officer, Social Sectors, Delegation of the European Commission to the Republic of Uganda, 19 May 2008.
178 Ibid. and WHO (2008): 1. The same view is expressed by HEPS-Uganda (2007): 16, referring to the inefficiency in National Medical Stores supply chains, the expiry of ARV drug stocks worth $800,000 and the apparent misappropriation by third parties of drug shipments destined for the country's health centres.
179 See HEPS-Uganda (2007): 12–14. According to the same source, the grants were later restored, after the establishment of a new, interim fund management system. WHO (2009) also reports on problems with the disbursement of Global Fund grants to treat tuberculosis (http://www.who.int/GlobalAtlas/predefinedReports/TB/PDF_Files/uga.pdf).
180 For example, see WHO (2008), as well as press coverage in *Business Week* (2008): 1, referring to an AIDS patient in the Kasasa area who has to walk seven miles to receive treatment. See also HEPS-Uganda (2007): 15, reporting on patients in the Kalangala district who have to travel between six and twelve hours by boat to access HIV treatment.
181 WHO (2008): 1.
182 Interview with John Magezi, Ibale & Co., Advocates, Kampala, 15 May 2008.
183 Interview with C. Kityo.
184 Ibid.
185 Ibid and WHO (2008): 2.
186 Interview with C. Kityo.
187 See MoH (2002): 7–9.
188 HEPS-Uganda (2007): 11.
189 HEPS-Uganda (2006): 27. The report then specifies that the AIM programme has effectively closed down since the drafting of the report, leaving a number of HIV/AIDS initiatives without any further funding.
190 See HEPS-Uganda (2008a), referring to MoH estimates of HIV/AIDS increases by 2020 (for the exact figures, see above, in the introduction to this chapter).
191 Ibid.
192 Ibid.
193 See Request by MTTI to UNCTAD of 16 January 2008, referring, as the object of analysis, to Uganda's intellectual property policies.
194 See HEPS-Uganda (2008a).
195 According to Quality Chemicals staff, the joint venture has plans to export its production to the partner States of the EAC, southern Sudan and eastern parts of the Democratic Republic of the Congo (interview with G. Baguma).
196 Interview with Ravi S. Reddy, Chief Operating Officer, Quality Chemicals, 10 November 2009.
197 See article 70.8 of the TRIPS Agreement.
198 Personal interview with Dr. Yusuf Hamied, CEO, Cipla.
199 Interview with Ravi S. Reddy.

[200] Interview with Dr. Joseph Rubamela, Acting Director, Product Development, UIRI, 9 November 2009.
[201] Interview with Julius Ecuru, Assistant Executive Secretary, UNCST, 11 November 2009.
[202] Interview with Dr. Joseph Rubamela, 9 November 2009.
[203] Interview with Julius Ecuru, 11 November 2009.
[204] Interview with George Baguma, 17 May 2008.
[205] In this context, it should be noted that countries such as India approve drugs that meet a domestic quality and GMP standard, which is slightly below WHO standards, but which nevertheless guarantees drug safety and efficacy. For developing country producers, it is very difficult to immediately comply with WHO standards. Domestic standards such as those used India provide an opportunity for transition of local producers to WHO standards. For a detailed discussion of the variety of existing national regulatory standards, see Kourilsky P and Giri I (2008). Safety standards: An urgent need for evidence-based regulation. *Surveys and Perspectives Integrating Environment and Society (SAPIENS)*. 1 (2) (http://sapiens.revues.org/index219.html).
[206] Telephone interview with Dr. Lembit Rägo, Coordinator for Quality Assurance and Safety: Medicines, Essential Medicines and Pharmaceutical Policies, WHO, on 3 June 2009; and e-mail communication of 8 June 2009 to the author from Deus K. Mubangizi, Technical Officer, WHO Prequalification Programme, as authorized by the Executive Secretary/Registrar of NDA, Apollo Muhairwe.
[207] Figures from e-mail communication by Deus K. Mubangizi/Apollo Muhairwe.
[208] Telephone interview with Dr. Lembit Rägo. In 2005/06, total revenue for NDA amounted to 5,868,000,000 Ugandan Shillings (e-mail communication by Deus K. Mubangizi/Apollo Muhairwe), approximately $2,705,000.
[209] See, for example, European Commission (2008). Pharmaceutical sector inquiry: preliminary report, DG Competition. (http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf). See also the intense debates in Switzerland and the United States on the pros and cons of admitting parallel imports of patented pharmaceuticals from neighbouring countries in order to stop the skyrocketing of drugs prices.
[210] See Reichman JH (2009). Rethinking the role of clinical trial data in international intellectual property law: the case for a public goods approach. *Duke Law Journal.* Section II. D. 2: 26.
[211] See WTO (2002).
[212] HEPS-Uganda in this context notes that pharmaceutical products are inventions that are, for a transition period, not patentable, and suggests a stand-alone provision to this effect. See HEPS-Uganda (2008b). Uganda can have a better patent law than this draft. *Medicines Access Digest: A Quarterly Newsletter of HEPS Uganda*. 4 (1): 4–5.
[213] Unavailability of patent protection in this sense may take several forms, such as through express amendments to the legal infrastructure, the suspension of the application of patent provisions or the mere non-enforcement of granted rights.
[214] For details, see article 70.8 (b), TRIPS Agreement, as well as UNCTAD-ICTSD (2005): 766–772.
[215] The mailbox obligation already applied to LDCs during the original transition period (i.e. up to 1 January 2006). This follows from TRIPS article 70.8(a), which obligates all WTO members to apply the mailbox, "notwithstanding the provisions of part VI" of TRIPS. The provisions of part VI contain precisely the LDC transition period under article 66.1. Under the 2013 and 2016 extension decisions, it was this very same transition period under article 66.1 that was extended into 2013 (i.e. on the implementation of TRIPS obligations in general) and 2016 (i.e. on the implementation of TRIPS provisions on patents and the protection of undisclosed information in the area of pharmaceutical products). The extension decisions expressly refer to the LDC transition period "under article 66.1" of the agreement, i.e. the transition period under which LDCs had to respect the mailbox obligation under article 70.8(a). This reference has to be understood as carrying over into 2013/2016 the original mailbox obligation under the original transition period. While the 2013 decision only refers to TRIPS articles 3–5 as remaining obligations for LDCs, it makes clear in its heading that what is being extended is the transition period as subject to the mailbox obligation.
[216] See the introductory clause in article 70.8 of the TRIPS Agreement (emphasis added).
[217] Patents Act, chapter 216 of the Laws of Uganda, as entered into force on 15 October 1993.
[218] This interpretation is supported by WTO (1997). Appellate Body Report on *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*. AB-1997-5, WT/DS50/AB/R. 19 December, where the Appellate Body stressed the importance of an interpretation that remains close to the express language of the TRIPS Agreement, in order to not add any new commitments to a carefully negotiated balance of rights and obligations. The drafters of article 70.8 of the TRIPS Agreement were aware of the possibility for LDCs to suspend patent protection for pharmaceutical products after the entry into force of the WTO Agreement, following the authorization under article 66.1 of the TRIPS Agreement (i.e. the original transition period for LDCs). Nevertheless, they opted for the current version of article 70.8 with its limited scope of application. Construing a mailbox obligation for those LDCs that upon entry into force of the WTO Agreement did make pharmaceutical patent protection available but later chose to suspend it would be opposed to this intent of the drafters of the TRIPS Agreement.
[219] See paragraph 2 of the decision.
[220] See HEPS-Uganda (2008b): 5.
[221] As of June 2002, 73 per cent of patent invalidation claims initiated by generic producers in the United States had been successful, see United States Federal Trade Commission (2002). *Generic Drug Entry Prior to*

Patent Expiration: An FTC Study. Washington DC, USFTC: 16. Between 2000 and 2007, generic competitors prevailed in 75 per cent of the final opposition and appeals decisions rendered by the European Patent Office, and in 62 per cent of patent litigation cases in EU member States; see European Commission (2008): 10–11.

222 Interview with Kyomuhendo Bisereko, Registrar General, URSB, 14 May 2008.

223 Information provided by Jeroline Akubu on 26 June 2009.

224 Stakeholder discussion on 26 June 2009.

225 See section 3 (patents) of the Protocol on Patents and Industrial Designs within the Framework of the African Regional Industrial Property Organization, as adopted on 10 December 1982 at Harare (http://www.wipo.int/clea/en/text_pdf.jsp?lang=EN&id=4110).

226 See http://www.aripo.org/index.php?option=com_content&view=article&id=18&Itemid=55.

227 See UNCTAD (2008): 14.

228 National legislation in developed countries has traditionally defined "invention" as not comprising, inter alia, discoveries and scientific theories (see, for instance, article 52 (2)(a) of the European Patent Convention). The reason for the exclusion of discoveries lies in the basic rationale of patent protection, i.e. to reward human ingenuity and creativity as a contribution to the advancement of humankind. The inventor in exchange for his efforts and readiness to make his invention available to the benefit of society is granted a reward, i.e. a monopoly to exploit the invention over a limited period of time. Mere discoveries including, arguably, substances found in nature, need not be deemed under patent law as deserving of such a reward (even though some national laws do make patent protection available to discoveries). Discoveries do not result from anyone's ingenuity or creativity.

229 See Correa C (2000). *Integrating Public Health Concerns into Patent Legislation in Developing Countries*. The South Centre: 15–16.

230 UNCTAD (2008): 16.

231 Law 24.481, as amended by Law 24.572, consolidated text approved by Decree 260/96, of March 20/96.

232 See the discussion in the CIPIH Report. April 2006. Geneva: 130–134.

233 See UNCTAD (2008): 31–32.

234 See Thomas JR (2005). *Pharmaceutical Patent Law*. Washington DC, BNA Books: 177–181. According to Federal Circuit case law (*In re Dillon*, 1990), structural similarity between the claimed and prior art compound establishes a prima facie case of obviousness if in addition, there is a suggestion or motivation for the inventor to make the new compound with a reasonable expectation of success, and if the method of making the claimed compound was known to, or rendered obvious by, the state of the art (Thomas, 2005: 181). As regards the unexpected character of similar structures (in the context of the inventive step test), the May 2007 United States Supreme Court decision in *KSR International Co. v. Teleflex Inc. et al.,* 550 U.S. (2007) suggests that combining the relevant elements may be a logical, common sense step that the person skilled in the art would have taken in due course, based on his/her technical know-how and despite the lack of any published single prior art reference directly on-point. This stiffer standard could make it very difficult to continue the patenting of minor variant derivatives in future United States patent law.

235 See section 3 (d) of the Patents Act, 1970 (2005). This provision has been challenged before Indian courts by foreign pharmaceutical producers as being inconsistent with the TRIPS Agreement. The Indian High Court declined to rule on this matter, referring to the sole jurisdiction of the WTO Dispute Settlement Body. See Mueller JM (2007). Taking TRIPS to India – Novartis, patent law and access to medicines. *The New England Journal of Medicine*. 541–543. The authors of the present report believe that the Indian provision can be sustained. A detailed analysis, however, would go beyond the scope of this report.

236 Personal communication in May 2007 from Malcolm Spence, Technical Advisor, Intellectual Property/SPS, Caribbean Regional Negotiating Machinery, Bridgetown, Barbados.

237 Such use of the patented substance may consist, for example, in submitting the proposed generic substitutes to the DRA for bioequivalence testing, or in using the substance for the production of the generic producers' own test data to prove to the DRA that the generic version of the drug meets certain quality standards.

238 See WTO (2000a). Panel Report on *Canada – Patent Protection of Pharmaceutical Products*. WT/DS114/R. 17 March: para. 7.48, where the panel states that "approximately three to six-and-a-half years are required for generic drug producers to develop and obtain regulatory approval for their products. If there were no regulatory review exception allowing competitors to apply for regulatory approval during the term of the patent, therefore, the patent owner would be able to extend its period of market exclusivity, de facto, for some part of that three to six-and-a-half year period".

239 The WTO *Canada – Pharmaceuticals* Panel held that regulatory exceptions as used by Canada are compliant with the TRIPS Agreement.

240 See WTO (2000a): para. 7. 46.

241 125 S. Ct. 2372 of 13 June 2005.

242 See the discussion of this decision in Abbott FM (2006). Intellectual property provisions of bilateral and regional trade agreements in light of U.S. federal law. Issue paper no. 12. UNCTAD-ICTSD. Geneva: 8 (http://www.iprsonline.org/resources/docs/Abbott per cent20- per cent20US per cent20bilateral per cent20and per cent20regional per cent20trade per cent20agreements per cent20- per cent20Blue per cent2012.pdf). The Supreme Court based its reasoning on the express language of the United States regulatory review exception, which refers to uses "reasonably related to" the development and submission of information required for marketing approvals of drugs or veterinary or biological products.

243 In the *Merck v. Integra Lifesciences* case, Merck used compounds patented by Integra Lifesciences in order to find out more about potential new medical indications, but abandoned these activities as the patented substance revealed unpromising in this regard. Integra sued Merck for patent infringement. See Garrison: 58. A more narrow reading of the United States regulatory review exception would have found Merck liable for patent infringement, as its use of the patented substance never actually contributed to a request for regulatory approval.

244 Interview with M. Oteba.

245 Interview with G. Baguma.

246 Arguably, the description of pharmaceutical content relates to mere facts, lacks any personal creation by the producer and may therefore be excluded from copyright protection.

247 See draft article 31*bis*.3, TRIPS Agreement. In essence, these producers are not subject to the limitation that the compulsory license in the exporting country will only authorize production of the amount necessary to meet the needs of the eligible importing member. Thus, generic producers located within such a regional trade agreement are not limited in the amount of drugs they may manufacture under a compulsory license under the draft article 31*bis* system. In addition, these producers are not subject to the general requirement under the system that drugs produced for export have to be specially labelled, coloured and shaped in order to be identified as specifically produced under the system. Nor do they have to post on a website information regarding the quantities and the distinguishing features of their products. Finally, the re-exportation of drugs to other members of the regional trade agreement does not need to be notified to the WTO, as opposed to the situation when the exports come from a supplier outside the LDC-dominated trade agreement.

248 See UNCTAD (2008): 48–56.

249 Sections 58(2) and 61(3) provide the patentee with the possibility to argue against the granting of the license by the court, but confer no post-grant rights. Section 66(13) provides for the revocation of the license by the issuing ministry, as opposed to an independent review body like a court.

250 Under United States patent law, the patent holder may be granted injunctive relief, but needs to establish certain facts. See the 2006 United States Supreme Court decision in *eBay Inc v. MercExchange, L.L.C., 126 S. Ct. 1837 (2006):* the patent holder in order to be granted injunctive relief in a patent infringement suit has to demonstrate (1) that s/he has suffered irreparable injury; (2) that other remedies, including the payment of royalties, are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and the defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction (see ibid). Should the plaintiff be unable to demonstrate these cumulative requirements, s/he will have to tolerate continued use of the patented invention by the defendant, in exchange of a royalty payment. In practical terms, this situation corresponds to a compulsory license issued by the court. For an analysis of the eBay case, see Jacobs MJ and Melaugh DE. *eBay Inc. v. MercExchange*: copyright's promise for patent injunctions. http://www.techlawforum.net/patent-reform/articles/ebay-v-mercexchange-patent-injunctions/.

251 See article 13.7(a) of the Draft Patents Act of 2007; UNCTAD (2008): 47.

252 See section 15.6(a) of the Draft Bill; UNCTAD (2008): 46.

253 This may be inferred from a statement made by the Panel in WTO (2000a), at para. 7.94: "The ordinary meaning of the word 'discriminate' is potentially broader than these more specific definitions [i.e. in articles 3 and 4 of the TRIPS Agreement, regarding national treatment and most favoured nation treatment obligations]. It certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment. … The standards by which the justification for differential treatment is measured are a subject of infinite complexity."

254 See draft article 31*bis*.2, TRIPS Agreement.

255 Generic producers obligated to demonstrate bioequivalence may do so by measuring "the time it takes the generic drug to reach the bloodstream in 24 to 36 healthy volunteers. This gives them the rate of absorption, or bioavailability, of the generic drug, which they can then compare to that of the innovator drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug." See Pugatch MP (2006). Intellectual property, data exclusivity, innovation and market access. In: Roffe *et al.*, eds. *Negotiating Health: Intellectual Property and Access to Medicines.* London, Earthscan: 102.

256 See European Commission (2008): 10–11: between 2000 and 2007, generic competitors prevailed in 75 per cent of the final opposition and appeals decisions rendered by the European Patent Office, and in 62 per cent of patent litigation cases in EU member States. See also USFTC (2002): 16: as of June 2002, there was a success rate of 73 per cent in patent invalidation claims initiated by generic producers in the United States.

257 E-mail communication of 8 June 2009 to the author from Deus K. Mubangizi, Technical Officer, WHO Prequalification Programme, as authorized by the Executive Secretary/Registrar of the NDA, Apollo Muhairwe.

258 Ibid.

259 Section 16 of the Counterfeit Goods Bill. The bill in a separate provision defines "counterfeit goods" as "goods that are an imitation of something else with an intent to deceive, and includes any … goods which breach intellectual property rights".

260 The doctrine of equivalents serves to demonstrate the zone in which second comers can freely "work around" or "invent around" the claims of the patent without fear of infringement. Whether this doctrine is applied in a broad or narrow manner depends on national patent examination practice and in any case requires considerable experience in patent lawyering. For details, see UNCTAD (forthcoming, 2010). *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide*. United Nations publication. New York and Geneva.

261 See UNCTAD-ICTSD (2005): 621.

262 See section 3 of the Bill.

263 See *Business Standard* (2009). Ugandan move on patented drugs' import worries Indian companies. 6 March. See also IP Watch (2009). Anti-counterfeit and ethics violations challenge public health in Kenya. *Monthly Edition.* July: 5.

264 See, for instance, at http://www.wakili.com/Article3.html.

265 Gazette Supplement No. 150, Legal Notice No. 115, Anti-Counterfeiting Act No. 13 of 2008; date of commencement: 7 July 2009.

266 See http://www.who.int/medicines/services/counterfeit/oYHUYLHZ HQIQGH KWP FRXQWHUIHLWP HGLFLQH1V RQH which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.").

267 See section 2 of the Kenyan Anti-Counterfeiting Act.

III. Intellectual Property and Access to Textbooks

1. Introduction

The UNDP's Human Development Report of 2007/08 shows an adult literacy rate for Uganda of 66.8 per cent, which ranks the country 111th out of 177 countries with data.[268] The combined primary, secondary and tertiary gross enrolment ratio amounts to 63 per cent of the total population, which places Uganda 125th out of 177 countries.[269]

The government's education-related expenditure represents an important part of the national budget: in 2007, 31 per cent of discretionary recurrent expenditure was spent on education, with 67 per cent of this being allocated to primary education (ages 6–14).[270] Primary schools receive all available textbooks from the government, while the latter's involvement at secondary (ages 14–20) and tertiary (university) education levels is minimal.[271] At those stages, students need to purchase their own books, but usually find them unaffordable.[272] This has resulted in widespread photocopying of textbooks at the country's universities.[273] The awareness of copyright implications in this regard is usually very low among students, teachers and government officials.[274]

The relationship between copyright and access to textbooks and educational materials is complex, especially in developing countries. Copyright provides authors with certain economic and moral rights that many view as essential incentives to engage in creative activity. While the economic rights (such as the right to prevent others from copying or disseminating protected works) may be less important for certain scientific authors who seek academic recognition more than income,[275] publishers consider copyright (as licensed from the author) an important source of income to sustain their business, at least as far as books for secondary and tertiary education are concerned, where the government is not an assured buyer of their publications.[276] The sale of textbooks is particularly important for Ugandan publishers, as 95 per cent of the country's publishing market come from the educational sector.[277] This may be explained by the fact that reading fiction books is not typically part of Ugandans' everyday lives.[278]

On the other hand, prices of textbooks are unaffordable for most Ugandan students, who resort to large-scale photocopying of textbooks to an extent arguably not allowed under copyright law. If copyright were enforced more efficiently, this would result in serious problems by students to access textbooks needed for their education. The existence of numerous photocopy machine posts around universities attests to the widespread practice of Ugandan students to copy textbooks.[279]

Additional copyright issues arise in the digital environment. The lack of fully equipped libraries at universities and elsewhere could be addressed through the accessibility of online scientific articles, provided Internet connectivity is guaranteed. While the (partial) reproduction of a hard copy book for private use has been recognized in many countries under the traditional fair use doctrine or under specific exception clauses, digital copies may be reproduced at perfect quality and in any quantity, and disseminated widely, without the authorization of the copyright holder. The digital environment thus enables, in practice, uses of copyrighted materials that were traditionally not included in personal use or fair use provisions. This has raised concerns among content providers about the loss of market shares. The corresponding introduction of technological protection measures (TPMs) to block free access to copyrighted materials has been criticized, on the other hand, for making impossible certain uses that were traditionally exempted from copyright protection under private use provisions or the fair use doctrine.[280]

It is clear from the above that policymakers need to strike a balance between the interests of copyright holders and the users of protected content. Section 4 of this chapter will seek to provide an analysis of the existing Ugandan legislation in this regard.

2. Institutional set-up and objectives of the government

Article 41 of Uganda's Constitution of 1995 provides for the freedom of access to information. The ministry directly involved in education and the procurement of textbooks is the Ministry of Education and Sports. It has the mandate to "plan, formulate, analyse, monitor, evaluate and review policies, provide technical support and guidance, and set national standards for the Education Sector."[281]

Its stated mission is to "provide technical support, guide, coordinate, regulate and promote quality education and training to all persons in Uganda for national integration, development and individual advancement".

The ministry's Education Planning Department sets as an objective to ensure pass rates in literacy and numeracy in primary education and pass rates in English, mathematics, science and information technology in post-primary education.[282]

Finally, the ministry's Instructional Materials Unit has the mission "to coordinate activities towards the acquisition, procurement and dispatch of instructional materials."

To this effect, the Instructional Materials Unit establishes lists of approved textbooks for pupils as well as of teachers' guides.[283] This list also shows the publishers (both domestic and foreign) from whom the books are purchased. In general, the ministry makes available funds to the schools or the districts to purchase the approved textbooks directly from the publisher.

Taking into account that learning materials may also be available in electronic form, it also seems appropriate to refer, in this section, to the objectives of the Ministry of Information and Communications Technology. The link between education and ICTs was clearly expressed by the Uganda Law Reform Commission (ULRC) in the context of reforming the country's copyright law, stating that "access to open source software, digital materials, materials online, etc. is essential for developing countries as they increasingly use distance learning to reach their populations".[284]

The Ministry of Information and Communications Technology in October 2003 issued a National Information and Communication Technology Policy.[285] In line with the identification of ICTs as a priority area for attracting investment,[286] the ICT Policy "recognizes the important role information and ICT play in national development" and emphasizes the contribution of "access to information" to national development, "especially human development and good governance".[287] More specifically, the ICT Policy has a number of policy objectives that relate to the government's objectives in the education sector and to copyright policy, such as:

> (c) To promote and enable the building and establishment of an appropriate infrastructure that supports ICT development and at the same time achieve Universal Access in Uganda.
> …
> (g) To facilitate the broadest possible access to public domain information.
> …
> (m) To accord due regard, recognition and protection to intellectual property rights.

The ICT Policy also reflects the difficulty of providing copyright protection to digital material without at the same time blocking legitimate access to information online. One of the proposed strategies to stimulate production, storage and dissemination of national information is the following: "In receiving and updating the relevant laws, the promotion of principles underlying exemptions to the protection of intellectual property rights will be taken into account, such that the rights of all citizens to access and use public domain information are not prejudiced."[288]

A strategy for the establishment of a desirable and enabling legal framework equally refers to the need for balance between intellectual property protection and access to information, as follows:

> Review existing laws, taking into account other suitable or relevant laws elsewhere, and design a new legal framework that promotes and supports ICT policy objectives, while taking cognizance of major cross-cutting issues like privacy, security, intellectual property rights and copyrights, without unduly restricting public access to information.[289]

By contrast, the ICT Policy does not refer to the Ministry of Education and Sports as one of the stakeholders whose policies should be taken into account in the development of ICT policy.[290] Nevertheless, the ICT Ministry considers the education sector to be among those where increased use of ICTs will generate the most important benefits.[291]

Finally, reference should also be made to the URSB, whose main objectives are to:[292]

- Administer and give effect to the relevant laws (including intellectual property laws);
- Provide registration services (including for patents, trademarks and copyright) and collect and account for all revenue provided for under those laws;
- Advise the government on matters relating to registration services under the relevant laws;
- Assist the government in the formulation of policy relating to the collection of revenue.

Roughly 80 per cent of the URSB's intellectual property-related work falls into the area of trademarks, but very little of it regards copyright.[293] A private lawyer expressed the opinion that trademarks are also better monitored and thus better protected than patents and copyrights.[294] Copyright registration with the URSB is not a substantive requirement to claim protection, but a formal requirement serving basically evidentiary purposes.[295] At the URSB, the number of staff handling the registration, administration and enforcement of all IPRs is very low.[296] Interviewed stakeholders agreed that Uganda is facing a serious lack of IPR enforcement.[297] There is, for the time being, no special unit within the police force to deal with IPR enforcement, and the judiciary is not trained on intellectual property law issues.[298]

This being said, it should not be overlooked that the enforcement of copyright, as the enforcement of other categories of intellectual property, remains predominantly the responsibility of the right holder. As stated in the preamble to the TRIPS Agreement, intellectual property rights are private rights. Copyright holders may expect state authorities to put at their disposal the government machinery to assist them in the enforcement of their claims; however, it is up to copyright holders to initiate enforcement proceedings. The awareness of copyright issues and possibilities of enforcement seems to be limited among domestic publishers.[299] As long as right holders do not initiate enforcement proceedings, the courts are not required to take any action, despite their general awareness of the copyright piracy problem.[300]

This situation requires urgent attention by the Ugandan authorities. Effective copyright enforcement is not only a matter of meeting international obligations, such as the enforcement provisions contained in the TRIPS Agreement, which Uganda as an LDC will

have to implement after 1 July 2013.[301] It is also in the country's national interest to promote an indigenous publishing industry that can encourage local writers and promote a reading culture throughout the country. While foreign publishers play an important role in Uganda's education sector, there are at least two domestic publishers (Fountain Publishers Ltd. and Mukono Bookshop Printing & Publishing, Ltd.) involved in the supply of the government with primary education textbooks.[302] Fountain Publishers also play an important role in secondary education textbooks. Next to strengthened copyright enforcement, there should be efforts to raise awareness among the population of the potential benefits that effective copyright protection and enforcement may bring to the local economy. This goes beyond the access to textbooks context, as local musicians have been voicing concerns about lost economic opportunities due to unauthorized copying of their music.[303] In order to improve copyright holders' own understanding of their rights, awareness activities should include the training of right owners, collective societies (where existent) and lawyers on the legal means available for the enforcement of IPRs.

This being said, it is understood that the particular Ugandan context requires much more than the strengthening of rights enforcement and awareness raising activities. Mechanisms need to be developed to ensure that the benefits of copyright protection are not limited to the intermediaries (i.e. the publishers), but extend to those for whom copyright protection has been intended: the creators (i.e. the authors and, beyond the textbook context, composers and performers of music) as well as the general public (i.e. their access to learning, scientific and cultural materials). The current drafting in Uganda of copyright regulations could provide a tool to ensure an equitable attribution of royalties to authors and publishers through collecting societies (which at the time of writing did not exist), according to international guidelines established by the International Confederation of Societies of Authors and Composers (CISAC).[304] According to sections 42(1)(d), 74–78 of the Copyright Act, the Copyright Registrar, who is located within the URSB, shall "discipline" collecting societies through measures such as the inspection of "any books, records or documents" that relate "to the operations of the society". This could include, for example, ensuring that collected royalties are actually passed on to the authors and publishers, and that royalties are fairly distributed between authors and publishers. Such inspections are difficult tasks and require some expertise. There is a need to build those capacities at the URSB, as well as capacities related to the enforcement of copyright protection.

While these measures to strengthen copyright enforcement are necessary to reward creators, it is very important to make sure that improved copyright enforcement has no negative impact on Ugandan users' ability to access educational and scientific materials. As will be shown in section 4 of this chapter, the Copyright Act in its current version lacks precision in addressing copyright exceptions and limitations, thus missing opportunities to facilitate access to reading materials within the boundaries of Uganda's international commitments. The strengthening of copyright enforcement without a parallel adjustment and improvement of certain copyright exceptions would likely result in decreased access opportunities for copyright users, such as students and researchers, who for the time being have been relying on activities that have to be considered copyright infringements under the current law.

For these reasons, we recommend, on the one hand, that the government undertake serious efforts in training and building capacities of copyright owners, state authorities and the judiciary in the enforcement of copyright. Right holders need to understand their primary responsibility for the initiation of copyright enforcement proceedings. The judiciary, the customs authorities and the police need to have the capacity to respond to rights holders' requests. Finally, there should also be capacity-building activities for URSB staff in respect of both copyright enforcement and inspection of collecting societies, and possibly an increase in the number of staff charged with these issues.

In this context, the government may seek technical and financial assistance from OECD countries, which have recently put considerable emphasis on the worldwide improvement of intellectual property enforcement capacities. WIPO should also be approached in this respect. Financial assistance could also be requested from private bodies, such as CISAC. In addition, the government should request OECD countries' and WIPO's assistance in raising the public's awareness of the potential benefits of a well-balanced copyright law for the promotion of domestic artists. Some of the interviewed stakeholders emphasized the importance of such awareness raising activities in an environment that generally lacks appreciation for the cultural contribution made by authors and performers.[305]

At the same time, however, the government should ensure a revision of the Copyright Act to include more flexible and appropriate provisions on copyright exceptions (the relevant exceptions are discussed in detail below). Merely enforcing the Copyright Act in its 2006 version will likely aggravate access problems in Uganda. Section 4 below will provide more details in this regard.

3. Access to textbooks and main obstacles

Besides the above-mentioned public authorities, other stakeholders play important roles in the access to textbooks context. As indicated above, the Ministry of Education has committed itself to make funds available to schools to purchase textbooks for primary education from foreign and domestic publishers. In this regard, publishers have secured their market and are not concerned about subsequent copying of the sold books. This only changes where the schools use the government funds to purchase cheaper, unauthorized copies of needed textbooks, a situation that occurs in some parts of the country, but reportedly does not constitute a frequent practice.[306]

The copying of primary education textbooks is still necessary, because even in primary education, not every pupil has his/her own textbook, the ratio being better in urban than in rural areas.[307] According to World Bank empirical evidence, the availability of textbooks has an impact on sixth grade students' performance in subjects such as English and mathematics.[308] In this context, it makes a difference whether the books are provided directly to the pupils to take home or are shared among several pupils and otherwise kept in the teachers' offices. The lack of a sufficient number of books has resulted in 75 per cent of sixth grade pupils depending on shared school textbooks for both mathematics and English.[309] According to World Bank sources, teachers are hesitant to actually use the existing books during class, due to the small number of books available.[310] Others have observed that, while the number of available textbooks would be sufficient to provide (shared) access by pupils, teachers tend to regard the books as being too valuable to be used by pupils.[311]

In secondary education, the government has recently initiated a World Bank-funded programme for the procurement by the Ministry of Education and Sports of textbooks worth $190 million.[312] However, publishers' associations have criticized the new arrangement for mandating the ministry to choose one book title per subject on a country-wide scale, as opposed to the earlier situation, under which the schools themselves were given the freedom to select the books. According to that criticism, the new arrangement would create a monopoly, as only one of the competing publishers (i.e. Fountain, Longhorn, Macmillan, St. Bernard and MK) would be authorized to supply secondary education textbooks throughout Uganda.[313] According to the ministry, however, the new arrangement, which favours the lowest bidder, seeks to ensure that a maximum number of books can be purchased.[314]

As far as university education is concerned, the situation differs considerably. Government subsidies for tertiary education textbooks were stopped in 1988.[315] Due to most students' inability to purchase originals, and due to their preference to resort to photocopying, domestic publishers have neglected the market for tertiary education.[316] Photocopying is

generally encouraged by professors and libraries, as it constitutes the only efficient means to provide students with access to necessary learning materials.[317] Often, university lecturers improve their income by installing their own photocopy machines, on which students are free to photocopy any amount of textbooks or articles against payment of a fee. The owner of the photocopy machine pays a percentage of his income to the university or faculty, for the right to use university premises.[318] There is in general no awareness among students or the owners of the photocopiers of the copyright implications of their activities, neither with respect to liability for infringement, nor in terms of lost sales opportunities for the (local or foreign) publishing industry. Due to the quasi-total absence of any copyright enforcement action, the motivation of photocopy machine owners to pay copyright levies to the publishers is non-existent.[319] In addition, even if such motivation existed, making such royalty payments would meet practical problems, as there are, for the time being, no collecting societies in Uganda that could collect royalties on behalf of the publishers and authors.[320]

In order to better administer and enforce copyright, the Copyright Act provides for the creation of collecting societies.[321] More details are contained in the Copyright Regulations, which have not yet entered into force and which are not currently available as a public document. Interviewed stakeholders have lowered expectations about the positive impact of collecting societies on the effective enforcement of rights holders' interests, citing examples from other African countries, where established collecting societies have failed to transfer the collected royalties to the copyright holders.[322]

Not all interviewed stakeholders necessarily agreed on the main obstacles to general access to textbooks in Uganda. While many view price as an important issue, considering the low purchasing power of the average Ugandan, at least one domestic publisher claimed that due to their low production costs in Uganda, their products would match the prices of photocopied books,[323]but students would prefer photocopies in case they only need certain (sometimes minor) parts of a book, or because photocopies facilitate the preparation of "pamphlets", i.e. course packs made up of reading material taken from several sources and often not displaying the entire text of the original, but bullet point summaries.[324]

Other stakeholders referred to the lack of a reading culture in Uganda,[325] which arguably results in a smaller demand and thus higher prices for those books that are actually available. While this argument seems to mainly relate to fiction books, the observed hesitation of teachers to distribute available textbooks to pupils and to base their classes on textbooks (see above) may partly be explained by the absence of a reading culture, even among teachers.

It is difficult to assess to what extent copyright contributes to higher prices of textbooks in Uganda. What appears clear is that copyright currently does not prevent access, because it is widely ignored and not enforced. While the present report has to take this situation into account, it seeks to suggest more sustainable solutions, in harmony with Uganda's multilateral intellectual property commitments, to find a fairer balance between users' right to access information (as enshrined in Uganda's Constitution) and the rights of Ugandan and foreign artists to benefit from their creative works, as well as the interest of the Ugandan people to promote domestic writers and, more broadly, creative industries.

Interviewed stakeholders expressed a number of ideas about ways and means to increase the availability of textbooks for all levels of education, and how to strike an appropriate balance between the interests of users (mainly university students) and publishers and authors. Addressing the general concern that most books are unaffordable for Ugandans,[326] it was suggested to increase the domestic, low cost production of foreign textbooks, under licence from (foreign) holders of the copyright in Uganda.[327] At the same time, it was acknowledged that copyright enforcement was a major problem in Uganda and that photocopying of textbooks would continue in the future.[328] In this context, the National Book

Trust of Uganda (NABOTU), which represents local publishers, booksellers and libraries, welcomed the fact that under the 2006 Copyright and Neighbouring Rights Act, copyright infringement is sanctioned as a criminal offense.[329] Furthermore, it was observed that photocopy machine owners have benefited significantly and could be asked to pay a small royalty to the author and/or publisher for each copied book.[330] Here again, the lack of copyright enforcement is likely to provide a serious obstacle to such solutions.

NABOTU pointed to the current lack of electronic distribution of content to users. In the context of a project sponsored by the Canadian International Development Research Centre, NABOTU and a number of other institutions will:

> … conduct a comparative study of the viability of publishing demonstration projects involving flexible licensing agreements in South Africa and Uganda. The team will help local publishers better understand and use alternative licensing and new business models that take advantage of the digital environment. The project is also expected to consider the statutory and regulatory environment that would best support the application of liberal licensing practices.[331]

By "flexible licensing", NABOTU is referring to "Creative Commons" types of licences, which they encourage publishers to use in order to take advantage of electronic publishing.[332] As a first result of the Canadian International Development Research Centre-funded project, the biggest Ugandan publisher has accepted making one of its textbooks available online under a Creative Commons licence (see table 1), authorizing users to reproduce the material for non-commercial purposes.[333] The problem here is that for the time being, this licence is not operational, because so far, no national Creative Commons licence has been developed for Uganda.[334] In order for a Creative Commons licence to be operational in a given jurisdiction, the core terms of the international types of Creative Commons licence have to be adapted to the particularities of the domestic copyright system of that particular jurisdiction.[335]

Table 1. Overview of the main types of licences available under Creative Commons

Type of licence	Must acknowledge original author	Allows redistri-bution	Allows user to tweak, change, or build upon your work	Non-commercial use	Derivate works	New creations must give licences on the same terms
Attribution	✓	✓	✓	✓	✓	
Attribution share alike	✓	✓	✓	✓	✓	✓
Attribution no derivatives	✓	✓		✓		
Attribution non-commercial	✓	✓	✓	✓	✓	
Attribution non-commercial share alike	✓	✓	✓	✓	✓	✓
Attribution non-commercial no derivatives	✓	✓		✓		

Source: http://creativecommons.org/about/licenses/

The lack of electronic distribution of content to users as observed by NABOTU follows from rather poor Internet connectivity throughout the country. While there is a reasonable number of Internet service providers that provide Internet and e-mail access in Kampala, access by medium- and lower-income populations in rural Uganda is technically difficult and therefore unaffordable for most.[336] In addition, the provision Internet access to schools is currently in infancy.[337] Consequently, most secondary schools do not offer any ICT-related training, and

where facilities are available, these have been considered as of inadequate quality.[338] Government employees receive ICT training, but in a rather uncoordinated manner, with variations in content covered by different training institutions.[339]

Despite these shortcomings, stakeholders familiar with the Ugandan context believe the dissemination of digital content has a huge potential for Uganda's efforts to increase access to reading materials.[340] According to the Uganda Investment Authority, investment in a better ICT infrastructure is a declared government priority.[341] Increasing Internet connectivity in Kampala is an encouraging factor, and over time, it is hoped that decreasing costs and improved technology will facilitate access even in Uganda's rural areas. A 2006 UNCTAD/ICTSD study on Southern African countries, where the development of ICTs is mostly comparable to Uganda, found that:

> New information technologies make it feasible to extend access to massive libraries of educational, scientific and cultural works, and as the technological costs of storing and manipulating information fall, even the least resourced learning institutions can potentially have something close to parity in terms of the information resources currently available in wealthier countries. Distance learning, already accounting for a significant portion of learning in the South, will increasingly rely on digital means for reach and delivery.[342]

4. Analysis of the intellectual property legislative framework relevant to access to textbooks (copyright and related rights)

4.1 Background

The objective of this chapter is to examine to what extent Uganda's copyright law is in line with the country's efforts to promote access by its citizens to textbooks. This means that the legal analysis has to take account of the situation on the ground, as identified in the stakeholder interviews. Stakeholders generally agreed that the unauthorized bulk copying of textbooks (and, in broader terms, copyright piracy including in the entertainment sector) will remain constant user practice in Uganda for years to come.[343] This seems a realistic assessment, considering the low purchasing power of most Ugandans, the widely perceived lack of a reading culture that is combined with a general lack of understanding of publishers' need to make economic benefits and an almost complete lack of copyright enforcement. Rights holders' associations like NABOTU acknowledge price-related access problems in the textbooks context and have indicated, through projects on flexible licensing, such as Creative Commons, their preparedness to experiment with new business models that seek to strike a balance between the interests of copyright holders and users. Uganda's Performing Arts Association has also recommended Creative Commons licences in the context of online music.[344]

The legal analysis and the recommendations made in this report seek to show what changes are required in Uganda's legal and institutional infrastructure to enable a mutually beneficial relationship between publishers and authors, on the one hand, and users on the other hand. While any legislative changes will have to be in harmony with Uganda's multilateral obligations, especially under the Berne Convention and, as of 2013, the TRIPS Agreement, we acknowledge the need to interpret the limitations and exceptions contained in these agreements with particular respect for the access to knowledge situation in Uganda, which considerably differs from those in OECD countries. Such an interpretation complements our proposal for improved copyright enforcement capacities and awareness creation (see section 2, above).

Uganda's Copyright and Neighbouring Rights Act was passed into law in 2006, replacing the 1953 Copyright Act that was based on the United Kingdom Copyright Act.[345]

Recommendations for the new Act were elaborated as of 2001 by a consultant contracted by the United States Agency for International Development and reviewed by a task force made up of various Ugandan stakeholders.[346]

The ULRC in its *Study Report on Copyright and Neighbouring Rights Law* refers to a number of reasons for the reform of Ugandan copyright law.[347] One of the major reasons in this respect is improved copyright enforcement, providing both civil and criminal remedies to address the piracy problem in the country. In addition, the report refers to "the need to protect the right of access to information", including in the digital area.[348] More specifically, it calls upon the lawmakers to consider, inter alia:

- "Special provisions in copyright laws permitting educational use of freely available material without payment or permission";
- Copyright law amendments permitting the "educational use of modern sources of information such as the Internet without infringing copyright";
- Whether new approaches to copyright would need to be developed for the digital environment.[349]

While it seems obvious that "freely available material" (i.e. existing in the public domain) may be accessed "without payment or permission", this chapter will analyse, in the following section, the extent to which the Copyright Act permits educational use of copyrighted materials without payment or permission, including in digital form. Particular emphasis will be put on those provisions that impact upon Ugandans' access to textbooks and study materials, i.e. provisions on fair use of works protected by copyright (section 15 of the Copyright Act) for the purposes of teaching and education, private personal use, use by libraries and assistance to visually impaired persons. In the context of this analysis, it will be appropriate to examine to what extent the Copyright Act addresses digital content. Considering the current lack of a sufficient number of hard copy textbooks in Uganda, wide access to online works could make an important contribution to the government's objectives in the area of education.[350]

4.2 Rights of the copyright holder under the 2006 Copyright Act

Section 5 of the Copyright Act lists the works eligible for copyright, covering, inter alia, works that are essential in the access to textbooks and knowledge context, such as articles, books, pamphlets, lectures, audio-visual works, electronic data banks, three dimensional works relative to geology, topography, architecture or science, or any other work in the field of literature, traditional folklore and knowledge, science and art in whatever manner delivered, known or to be known in the future. Section 4 specifies that only those works that are original (i.e. the product of the independent efforts of the author) shall enjoy copyright protection. This has important implications on the extent to which users may freely access certain information. For example, it is clear from section 4 that non-creative databases are not eligible for copyright protection. Such databases contain mere compilations of data that, while not requiring any creativity on behalf of their originator, may nevertheless provide important factual information for teaching, learning and scientific research. Databases are non-creative to the extent that they have been established following pre-determined criteria, according to which anybody would have developed a similar collection, for example certain catalogues, address books, price lists, or collections of scientific data following mandatory selection criteria.

Sections 9 and 10 of the Copyright Act lay down the economic and moral rights of authors in protected works (i.e. those works meeting the originality requirement under section 4 and falling under one of the categories enumerated in section 5). The economic rights enumerated in section 9 refer to the classical rights of reproduction (including publication and production), distribution to the public, performance in public and broadcasting. These rights

apply in the non-digital environment. As to the digital environment, it should be noted, at the outset, that Uganda is not a party to the WIPO Copyright Treaty (WCT) nor to the WIPO Performances and Phonograms Treaty (WPPT) (the "Internet Treaties"), which extend copyright into the digital area. Nevertheless, the Copyright Act in section 9(e) provides, as an economic right of the author, the exclusive right:

> … to communicate the work to the public by wire or wireless means or through any known means or means to be known in the future, including making the work available to the public through the Internet or in such a way that members of the public may access the work from a place and at a time individually chosen by them …

Similar language is employed under sections 8(4) on performers' rights and 14(4) on the rights of producers of sound recordings. This draws on the wording used in article 8 of the WCT and articles 10 and 14 of the WPPT, which extend the exclusive rights of authors, producers of phonograms and performers to digital works available on the Internet. Section 18 on the rights of broadcasting companies refers to the right to broadcast, which according to the definition in section 2 includes "services by wire or wireless means in such a way that members of the public access the fixation from a place and at a time individually chosen by them".

Thus, Ugandan copyright law extends the right of authors, producers of phonograms and performers to digital content.

4.3 Exceptions and limitations to copyright in the area of access to textbooks – introduction

For the digital environment, the WIPO Internet Treaties in their preambles stress the importance of copyright and neighbouring rights protection, but also recognize "the need to maintain a balance between the rights of authors (or performers and producers of phonograms) and the larger public interest, particularly education, research and access to information, as reflected in the Berne Convention".[351]

Considering the difficulties faced by Ugandan students and researchers to access affordable textbooks, the same need for balance also applies to the non-digital environment. It is the purpose of limitations and exceptions to copyright to help governments strike such a balance. In the digital context, parties to the WCT and the WPPT are authorized "to devise new exceptions and limitations that are appropriate in the digital environment".[352]

To the extent the Ugandan Copyright Act maintains the rights of authors and neighbouring rights as mandated under the Berne Convention and the TRIPS Agreement, the country appears free to follow this authorization under the Internet Treaties and devise exceptions and limitations to copyright and neighbouring rights specifically tailored to the digital area, despite the fact that Uganda is not a member of these treaties. In view of the enormous potential the Internet offers for dissemination of knowledge, such as through online distance learning courses, it seems extremely important to design such exceptions and limitations, with a view to ensuring the enormous benefits online distribution and availability of teaching materials may generate in terms of quick and affordable access, exchange of views and collaborative research.[353]

In the following sections, we will analyse to what extent the limitations and exceptions under the Copyright Act actually contribute to facilitating access to textbooks, learning and scientific materials in both digitalized and non-digitalized form. In line with the priority concern for electronic materials, as expressed by the ULRC in its *Study Report on Copyright and Neighbouring Rights Law*,[354] particular emphasis will be given to the digital environment.

Before examining the limitations and exceptions under Uganda's Copyright Act, it should be noted that no particular attention will be paid to a possible use by Uganda of compulsory licensing of the copyright reproduction and translation rights under the Appendix to the Berne Convention. First, Uganda has never deposited at WIPO a declaration availing itself of the faculties provided under the Berne Appendix. Second, the use of the Berne Appendix has been characterized as complex and burdensome, implying significant transaction costs and a waiting period of several years. Its limited scope has been criticized as a deterrent to potential licensees.[355] As compared to the Berne Appendix, it is submitted that a modern application of the exceptions as contained in the Copyright Act will more effectively promote access to textbooks in Uganda.

4.4 **The teaching exception** (Section 15(1)(c) and (d) of the Copyright Act)

The teaching exception consists of two separate provisions, stating that:

> (1) The fair use of a protected work in its original language or in a translation shall not be an infringement of the right of the author and shall not require the consent of the owner of the copyright where –
>
> > (c) A published work is used for teaching purpose to the extent justified for the purpose by way of illustration in a publication, broadcast or sound or visual recording in so far as the use is compatible with fair practice and acknowledgement is given to the work and the author;
> >
> > (d) The work is communicated to the public for teaching purposes for schools, colleges, universities or other educational institution or for professional training or public education in so far as the use is compatible with fair practice and acknowledgement is given to the work and the author.

While the introductory paragraph (1) makes clear that the exception has to be tested against the fair use criteria under section 15(2) (see below for discussion), paragraph (c) refers to the use "by way of illustration" of the copyrighted material, which arguably comprises the use of textbooks, and paragraph (d) addresses cases where the copyrighted work is communicated to the public in the form of sounds and images (see definition of "communication to the public") under section 2 of the Copyright Act).

The provision immediately relevant in the access to textbooks context is section 15(1)(c). It is closely based on the language employed in the teaching exception in article 10(2) of the Berne Convention. The decisive notion for determining the extent to which a textbook and other works may be reproduced is the "use by way of illustration", which has recently been criticized in the literature for lacking transparency.[356] The term "illustration" is rather vague, as the effective illustration of an academic or technical problem in the course of teaching may require the reproduction of an entire scientific article, or, depending on the case, it may suffice to reproduce only a fraction of a work. In addition, the requirement for the illustration to be part of another publication adds yet another layer of difficulty, as this seems to authorize the reproduction only by other authors, as opposed to the mere reproduction by students or teachers. A teaching exception in order to take into account the realities in Uganda should directly authorize the reproduction, to a certain extent, of teaching materials (inter alia textbooks) by the students themselves.

Finally, the provision leaves open the extent to which textbooks and/or scientific articles may be made available through the Internet for distance learning purposes, which may in the future become an important tool for developing country teaching institutions to bridge the current lack of hard copy books, including in libraries.

This lack of precision creates legal insecurity and may therefore also have been the reason for a number of developed countries to deviate, in their domestic copyright legislation, from using similar references. An example is the Australian Copyright Act,[357] which in its provision on fair dealing for purpose of research and study by broadly referring to "reproduction" includes the making of digital copies (see box 2 for the exact terminology of this provision).[358] A similar reference could be made in the Ugandan Copyright Act, because "reproduction" includes the making of copies in electronic form (see section 2 of the Copyright Act on the interpretation of the term "reproduction").

Producing digital copies of copyrighted textbooks under the teaching exception (either through electronic copying or through the scanning of hard copy documents) greatly facilitates the dissemination of these textbooks to the extent that students have access to computer hardware and a network. At the same time, students who have access to digital content may disseminate it further, either for free or in exchange for some remuneration. In either case, such further distribution would go beyond the scope of the teaching exception, the purpose of which is to provide access to learning materials in the specific context of a learning institution.[359] For this reason, digital copies produced at schools, while accessible for free to enrolled students, could be made to contain software that allows just one reproduction process, thus preventing further electronic dissemination. Whether a book is available in electronic form beyond the context of a specific educational programme is a decision that goes beyond the scope of a specific copyright exception and should only be made by the author or the publisher (for instance by making a book available through an open content licence such as Creative Commons). Technological measures may provide a tool to enable access to information in the context of a copyright exception, but to prevent, at the same time, the uncontrolled public dissemination of digital content beyond the scope of the exception.

Box 2. Fair dealing for the purpose of research or study in section 40 of the Australian Copyright Act

40.(1) A fair dealing with a literary, dramatic, musical or artistic work, or with an adaptation of a literary, dramatic or musical work, for the purpose of research or study does not constitute an infringement of the copyright in the work.

(1A) A fair dealing with a literary work (other than lecture notes) does not constitute an infringement of the copyright in the work if it is for the purpose of, or associated with, an approved course of study or research by an enrolled external student of an educational institution.

(1B) In subsection (1A) the expression "lecture notes" means any literary work produced for the purpose of the course of study or research by a person lecturing or teaching in or in connection with the course of study or research.

(2) For the purposes of this Act, the matters to which regard shall be had, in determining whether a dealing with a literary, dramatic, musical or artistic work or with an adaptation of a literary, dramatic or musical work, being a dealing by way of reproducing the whole or a part of the work or adaptation, constitutes a fair dealing with the work or adaptation for the purpose of research or study include:

(a) The purpose and character of the dealing;
(b) The nature of the work or adaptation;
(c) The possibility of obtaining the work or adaptation within a reasonable time at an ordinary commercial price;
(d) The effect of the dealing upon the potential market for, or value of, the work or adaptation; and

(e) In a case where part only of the work or adaptation is reproduced – the amount and substantiality of the part copied taken in relation to the whole work or adaptation.

(3) Notwithstanding subsection (2), a dealing with a literary, dramatic or musical work, or with an adaptation of such a work, being a dealing by way of the reproducing, for the purposes of research or study:

(a) If the work or adaptation comprises an article in a periodical publication – of the whole or a part of that work or adaptation; or

(b) In any other case – of not more than a reasonable portion of the work or adaptation; shall be taken to be a fair dealing with that work or adaptation for the purpose of research or study.

(4) Subsection (3) does not apply to a dealing by way of reproducing the whole or a part of an article in a periodical publication if another article in that publication, being an article dealing with a different subject matter, is also reproduced.

Source: Australian Copyright, Act (Consolidation), 27/06/1968 (30/07/2002), No. 63 (No. 63).

This Australian fair use provision is much easier to implement by the courts than section 15(c) of the Ugandan Copyright Act, due to its greater precision. The thrust of this provision differs slightly from that of section 15(c) of the Ugandan Copyright Act in that the Australian provision is not limited to reproductions used for teaching purposes, but applies to private research or study, comparable to section 15(1)(a) of the Ugandan Copyright Act. However, nothing prevents the Ugandan legislator from making a provision of comparable precision applicable to all students enrolled in (mostly tertiary) education programmes, to authorize them directly to make a certain amount of copies of needed teaching materials.

The Australian provision gives some guidance as to the legitimate amount of copies authorized for reproduction. In particular, it refers expressly to the reproduction of “the whole or a part” of a copyrighted work (section 40(2)). In general, the reproduction of “a reasonable portion” of the work is considered as constituting fair use of copyright (section 40(3)). Section 10 defines “reasonable portion” as a copy that, in general, does not exceed 10 per cent of the protected work (in pages or digital content). But section 40(2) as quoted above specifies that in certain cases, an amount of up to the entirety of the work may be reproduced. This provision expressly includes, among the criteria that determine fair use, “the possibility of obtaining the work or adaptation within a reasonable time at an ordinary commercial price” (section 40(2)(c)). Similar criteria, especially referring to affordability, could be introduced into Uganda’s Copyright Act, i.e. in section 15(2). This would allow a more flexible consideration of the amount of copies authorized under the teaching exception, rather than a rigid percentage that may not always reflect reality, depending on variations in books prices and availability. The current version of section 15(2) includes those elements traditionally used in United States case law to determine fair use; however, neither the Berne Convention nor the TRIPS Agreement prevent a member from devising exceptions in a way reflective of their particular needs, as long as the minimum requirements under the three-step test in article 13, TRIPS Agreement, are met. This test is briefly explained in box 3.

The first requirement (certain special cases) would seem to prohibit a copyright exception that authorizes bulk copying of textbooks in all cases. As in the Australian example, criteria like affordability and availability, within a reasonable amount of time, could serve to address this requirement on a case-by-case basis. Uganda could establish a minimum percentage of the protected work that would constitute a reasonable portion to be copied. Such a percentage would have to take affordability and availability in the Ugandan context into

account and could therefore be considerably higher than in the Australian example (i.e. 10 per cent).

Box 3. The three-step test in international copyright law

The "three steps" enumerated in article 9(2) of the Berne Convention refer to three requirements that need to be met in order for activities that would otherwise infringe upon the reproduction right to be legally justified. Under the Ugandan Copyright Act, this test is expressly mentioned in section 15(1)(j). In particular, exceptions to the reproduction right that Berne Convention parties provide in their national legislation:

- Need to be limited to certain special cases (step 1);
- Shall not conflict with a normal exploitation of the work (step 2); and
- Shall not unreasonably prejudice the legitimate interests of the right holder (step 3).

The three-step test thus restricts the Berne parties' freedom to limit, in their domestic legislation, the exclusive reproduction right. The TRIPS Agreement in article 13 makes the three-step test applicable not only to those exceptions that members provide to the right of reproduction, but also to those limitations to which members wish to subject other rights available under copyright, such as the right of translation, the right of communication of a work to the public and the right of public performance.

The second requirement (no conflict with a normal exploitation of the work) could arguably be quite stretched in case of large-scale copying of textbooks, as this would under normal circumstances deny important sales opportunities to the authors and publishers of textbooks. However, in the specific Ugandan context, the "normal exploitation" of a copyrighted textbook arguably consists of selling a fixed amount of copies to the government for distribution to schools and does not usually include direct sales of books to students and researchers. Authorizing the latter, under the teaching exception, to make photocopies of protected works will thus hardly impact upon the purchase contracts the publishers and/or authors have concluded with the government (Ministry of Education). While such an interpretation would obviously not seem appropriate in OECD countries, the situation is different in Uganda, where all interviewed stakeholders have acknowledged that unauthorized copying of textbooks is part of the Ugandan access to knowledge context, and even bridges access problems to an important extent. Ugandan copyright law has to reflect the actual situation on the ground and seek a solution that matches the local conditions. Such interpretation is supported by a recent declaration by the Max Planck Institute for Intellectual Property in Munich on "A balanced interpretation of the 'three-step test' in copyright law",[360] which states in its preamble that:

> In the context of global copyright regulation, harmonization has focused on securing right holders' ability to benefit from new modes of exploitation and business models. While international harmonization primarily serves the interests of copyright-exporting countries in a secure and predictable trading environment, **historic evidence, economic theory and the principle of self-determination suggest that individual states should have sufficient flexibility to shape copyright law to their own cultural, social and economic development needs. Copyright exceptions and limitations tailored to domestic needs provide the most important legal mechanism for the achievement of an appropriate, self-determined balance of interests at national level.** (emphasis added)

The third requirement (no unreasonable prejudice to the legitimate interests of the right holder) also has to be considered in the Ugandan context. What is "legitimate" in an OECD country may not be so in an LDC context, to the extent that enforcing the interest to realize the full benefit from sales of copyrighted textbooks would result in a denial to users to accede

to needed textbooks through photocopying or digital reproduction. It could be argued, from a rights holder's perspective that the third prong under article 13, TRIPS Agreement, only refers to the interests of rights holders, as opposed to users' interests. But such an interpretation would, first, ignore the collaborative approach shown by Ugandan rights holder interest groups such as NABOTU and the Uganda Performing Arts Association, which seem ready to find business models that accommodate users' limited resources to access creative products (see above). Second, such a positivist interpretation would, even in a developed country context, ignore the purpose of intellectual property protection to work to the "mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare", as enunciated under article 7, TRIPS Agreement, as the overall objective of intellectual property protection, including copyright. In even more express terms, the preambles to the WIPO Internet treaties (WCT and WPPT) recognize "the need to maintain a balance between the rights of authors (or performers and producers of phonograms) and the larger public interest, particularly education, research and access to information, as reflected in the Berne Convention".

Finally, the Max Planck Declaration cited above has proposed a new approach to the interpretation of the three-step test under copyright law, taking into account the legitimate interests of third parties. According to the declaration:

> 6. The three-step test should be interpreted in a manner that respects the legitimate interests of third parties, including:
>
> - Interests deriving from human rights and fundamental freedoms;
> - Interests in competition, notably on secondary markets; and
> - Other public interests, notably in scientific progress and cultural, social, or economic development.

Taking account of the need to balance exclusive rights and the public interest as enunciated in the WCT and WPPT Treaties, and following the suggestions in the Max Planck Declaration, Uganda is advised to amend its teaching exception under section 15 of the Copyright Act, along the lines of the Australian law discussed above, as applied to the specific Ugandan context. This would enable enrolled students and teachers to reproduce certain parts of textbooks in both hard copy and digital versions.

Depending on the affordability and availability of the original hard copy versions, even the reproduction of major parts could be justified, provided this constitutes the ultimate means for students to find access to needed textbooks. In this context, the subject matter covered in the textbook is of importance: while an English literature class would, presumably, need to copy an entire novel assigned, a science class may use only parts of a physics or biology textbook in any given year, for instance, which would make the copying of the bulk of the book much harder to justify.

Another consideration when assessing the legitimacy of copying large parts of textbooks should be the extent to which publishers are prepared to collaborate. Publishers willing to make available to schools full electronic copies of textbooks would seem entitled to prevent the unauthorized (electronic and reprographic) reproduction of large parts of these books, to the extent effective Internet access is actually available. They could be rewarded through the grant of a purchase agreement with the government for a specified number of textbooks. Procurement regulations would have to be amended accordingly, adding the availability of online versions of textbooks as a new selection criterion.[361] Technological protection measures could be used to prevent further uncontrolled dissemination of electronic copies.

As to the making of paper copies, it is suggested that the law provide for an obligation by the owners of photocopy machines to pay a levy to the right holder or the publisher, ideally

represented by an accountable collecting society. Such royalty payments would ensure that the legitimate interests of rights holders are not unreasonably prejudiced, in line with the third requirement of the three-step test. The payments would have to be minimal, reflecting the local purchasing power, as the operator of the photocopy machines would pass on these expenses to the users. The interest of the rights holders would be preserved not so much by the individual price per page, but through the sheer masses of photocopies that are made on a daily basis.

The preparation by students of course pamphlets, containing smaller excerpts of various textbooks, would qualify for the teaching exception and could be encouraged by schools, as an alternative to the reproduction of entire books. Secondary and tertiary education students should be made aware of available online versions of textbooks and should be subject to a university code of conduct to abstain from making full copies or copies of major parts of textbooks in those cases. Such a code could also inform students about the requirement to limit copying activities to those parts of the book absolutely needed to follow classes. Continuous disrespect of such a code of conduct could be sanctioned by the university, through fines and/or the cancellation of the student's enrolment, as appropriate.

Provided the above conditions are met, users would be able to continue their photocopying activities, only slightly more expensive than before, but justified under a domestic copyright exception and without potential liability, contributing (albeit modestly) to the viability of, inter alia, Ugandan authors and publishers. It is clear that for such a solution to be operational, there is a need to improve the appropriate enforcement of copyright, as suggested throughout this chapter.

4.5 The libraries and educational institutes exception (Section 15(1)(j) of the Copyright Act)

This provision is much more precise than the teaching exception, as it expressly refers to "reproduction", thus covering both reprographic and digital/electronic copying.[362] By encompassing "educational institute[s]", this provision fills an important void left by the teaching exception. As in the case of the teaching exception, the library exception should enable library users to access documents that are normally protected by copyright. These documents may be reproduced by the library or educational institute in digital form and be made available to the user. 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.

As opposed to the teaching exception, which should authorize students directly, a distinction needs to be made between reproduction by the educational institution/library to provide users with access, and further reproduction activities by the users themselves. The libraries and educational institutes exception should not authorize the user to make further digital copies and disseminate them beyond the library and educational institute context. This would be a decision to be made by the rights holder (author) or publisher of the textbook.

For example, Australia in its Copyright Act has a provision on the electronic dissemination by libraries of copyrighted materials to users, providing that materials may be made available:

> … online within the premises of the library or archives in such a manner that users cannot, by using any equipment supplied by the library or archives;
>
> (a) Make an electronic reproduction of the article or work; or
>
> (b) Communicate the article or work.[363]

As far as educational institutes are concerned, the extent to which these may make textbooks available to their students is arguably smaller than in the case of libraries. While

the making available of entire books by libraries will hardly affect the normal exploitation of the work by the authors and publishers, educational institutes such as public schools may constitute the principal targets of a publisher's sales efforts. To the extent a school can actually make digital copies available to students through computers, publishers may see a decrease in their sales of textbooks to these schools, even where students are not provided with paper copies but may only consult the textbooks online on school premises. Such a practice could threaten the "normal exploitation of the work", as referred to in section 15(1)(j)(i) of the Copyright Act. In practice, however, this situation will hardly occur, as Internet connectivity in most schools is still low and in any case not sufficient to replace the purchase, by the schools, of hard copy textbooks. As suggested above, publishers who are ready to make textbooks available online should be rewarded through a purchase agreement with the government for a specified number of hard copy textbooks.

Regarding the extent to which a user may make reprographic copies of the works available in a library or teaching institute, reference is made to the discussion of the teaching exception, above. In particular, criteria such as affordability and availability, and appropriate photocopy levies payable by the teaching institute or library to the rights holder, should be taken into account.

This will also ensure that activities under this exception meet the requirements of the three-step test, to which section 15(1)(j) of the Ugandan Copyright Act expressly subjects the libraries exception. The first step (i.e. limitation of the exception to certain special cases) is met through the qualification that such reproduction is not permissible on the part of every library, only those that are public, non-commercial or exist for scientific or educational purposes. The second step (i.e. no conflict with a normal exploitation of the work) is reproduced under paragraph (j)(i). As stated in the context of the teaching exception, this requirement seems to be met, under the specific Ugandan circumstances, as long as the private reproduction by students does not affect the overall purchase agreements between the government (or the schools) and the publisher.

The third step in paragraph (j)(ii), rather than referring to the "right" of the author, should be amended to follow the language employed under article 13, TRIPS Agreement, by replacing the term "right" by a reference to the "interests of the author of the work". Finally, the same provision should add a proviso based on the WIPO Internet Treaties, referring to the "larger public interest, particularly education, research and access to information, as reflected in the Berne Convention". Box 4 provides a brief legal analysis to support these recommendations.

Box 4. Differentiating the author's "rights" and "interests" under the libraries and educational institutes exception

The third step in paragraph section 15(1)(j)(ii) of the Ugandan Copyright Act deviates from the language employed under article 13, TRIPS Agreement (i.e. no unreasonable prejudice to the legitimate **interests** of the right holder) by stating that the "**right** of the author in the work" should not be unreasonably affected (emphasis added). It should be noted, in this context, that WTO panels interpreting the three-step test under patent and trademark law have focussed on the rights of the intellectual property holder under the first prong of the test, while broadening the analysis, under the third prong, beyond a purely legal assessment to possibly cover interests justified through "relevant public policies and other social norms".[364] By contrast, a WTO panel analysing the three-step test under copyright would not go as far, focussing its analysis of the third prong to the economic value of the exclusive rights conferred by copyright.[365] While the latter interpretation seems comparable to the Ugandan approach under section 15(1)(j)(ii) of the Copyright Act, the question arises how such an interpretation of the third step can possibly take account of legitimate third party interests. The current version of section 15(1)(j)(ii) of the Copyright Act seems to leave no basis for this, being limited to an assessment of rights owned by copyright holders alone.

While article 13, TRIPS Agreement (on copyright exceptions), as opposed to article 17 (on trademark exceptions) and article 30 (on patent exceptions) does not refer to the "legitimate interests of third parties", this has been criticized by renowned international copyright experts in the Max Planck Declaration, as follows: "The fact that third party interests are not explicitly mentioned in the three-step test as applied in copyright law does not detract from the necessity of taking such interests into account. Rather, it indicates an omission that must be addressed by the judiciary."[366]

This criticism is in line with the recognition, by parties to the WIPO Internet Treaties, that there is a "need to maintain a balance between the rights of authors (or performers and producers of phonograms) and the larger public interest, particularly education, research and access to information, as reflected in the Berne Convention".[367]

The reference to the Berne Convention and the need to "maintain" its balance in the digital area makes clear that this balance is not limited to the digital environment, but applies across the board to the entire copyright context. The legislative amendments suggested above provide a means to strike a balance between authors' rights and the public interest in education, research and access to information.

4.6 The private personal use exception (Section 15(1)(a) of the Copyright Act)

This provision, authorizing the "production, translation, adaptation, arrangement or other transformation of the work" for "private personal use only" is not reflected in the Berne Convention, but has traditionally been considered as an exception to copyright under many Berne parties' domestic legislation.[368] The terminology used in this provision leaves some doubt as to the meaning of "production", which is not defined under section 2 of the Act. Since this provision concerns the fair use of copyrighted material, it may be interpreted as justifying the "reproduction" of copyrighted material within the meaning of section 2 of the Act, for the purposes specified in section 15(1)(a). This implies the right to make digital copies for private personal use. For the purpose of clarity, it may be appropriate to substitute the reference to "production" in this provision by "reproduction", in line with the definitions provided under section 2.

The private use exception is subject to the three-step test under article 13, TRIPS Agreement, which generally applies to all copyright exceptions. This is important when seeking to determine the amount of a textbook that may be copied. Reference is made to the above analysis in the context of the teaching exception. Generally, the free-of-charge reproduction of entire works will be difficult to reconcile with the three-step test, but criteria such as affordability and availability should be taken into account and will authorize the reproduction of larger parts than in countries where books are more affordable and more readily available.[369] Major parts of books should not be copied where free online versions are available, or where such copying is not required to follow courses offered by an educational institution. Where copies are made, the author or publisher should either be compensated through royalties that reflect users' purchasing power (such as in the case of reprographic photocopying, as discussed above), or should provide his consent through an open content licence.

The private personal use exception does not include the right to disseminate the reproduced copies to third parties. As in the case of the teaching and the library exception, this exception is supposed to grant access, while maintaining control by the rights holder or publisher of further dissemination. Rights holders or publishers are free to have recourse to technological measures that limit the amount of copies to be made from a digital document.

4.7 The exception for the education of visually impaired persons (Section 15(1)(k) of the Copyright Act)

This provision exempts from copyright infringement any work that is "transcribed into Braille or sign language for educational purpose of persons with disabilities". While this exception, as any other copyright exception, is subject to the three-step test under article 13, TRIPS Agreement, it would seem that the very specific focus on education of visually impaired persons and methods of adaptation of the work limits this exception to certain specific cases, does not conflict with a normal exploitation of the work and does not do unreasonable prejudice to the legitimate interests of the right holder, even when applying conservative approaches to the interpretation of the three-step test. In addition, this Ugandan provision may provide some important guidance to the current efforts at the WIPO Standing Committee on Copyright and Related Rights to clarify the role of copyright limitations and exceptions in supporting the needs of the visually impaired.[370]

4.8 Addressing copyright exceptions in the digital environment – the use of technological protection measures

All of the above-mentioned exceptions would include, at least in the modified version suggested by this report, the possibility to make digital copies of protected works, by enrolled students, a teacher, a teaching institution or a library to make such copies available to their users, thus enhancing their potential to access textbooks, provided the necessary computer hardware and networks are available. At the same time, however, rights holders may be interested in limiting users' possibilities for further dissemination of digital works. As briefly discussed above, this may be done through TPMs.

TPMs usually consist of software designed to prevent either the access to certain digitalized works (e.g. by using passwords or encryption) or at least their copying (e.g. through software that may limit the number of copies that can be made).[371] In the exceptions discussed above, the latter type of TPMs would apply, as it was suggested that users (students, library users) be granted access to copyrighted materials without the possibility of further reproduction. In the ideal scenario, rights holders would make available their digitized textbooks to schools and libraries for providing access to students and readers (albeit with inbuilt reproduction control software to prevent further dissemination). The question arises how to address cases where the rights holder refuses to make digital copies available to these institutions, despite the fact that the intended uses fall under the teaching or the library exception. This could be the case, for example, if a publisher refused the request by a library to make available the digital version of a new textbook or scientific article, but asked for remuneration, even though the library could prove that it would make the digital content copy-proof, to prevent further dissemination. The TPMs used by the publisher would make access to the digitalized content impossible, even though the library would be entitled to such access under section 15(1)(j) of the Copyright Act. Instead, users would be guided to specially designed websites where they, in order to be granted access to copyrighted materials, would often face unilateral electronic contracts that impose waivers of statutory copyright limitations and exceptions.[372]

Before addressing this specific question, it should be noted that the use of TPMs to block fair uses of copyrighted materials goes far beyond the access to textbooks context. In medical science, for example, important methods of molecular research, such as the application of information technology to understand biological processes (a practice referred to as "bioinformatics"), seem to yield the best results where pursued through collaboration. This arguably requires new copyright exceptions, allowing for more copyrighted materials to be reproduced (often even verbatim) and shared among scientists.[373] While the design of such new exceptions specifically crafted for the digital environment is authorized under the WIPO Internet Treaties,[374] TPMs installed to prevent unlawful uses of copyrighted materials (e.g. commercial distribution) could at the same time be employed to prevent the use of such new exceptions (e.g. distribution for scientific exchange and feedback).

Being a non-party to the WIPO Internet Treaties, Uganda has no provisions on TPMs in its current Copyright Act. As the above examples show, however, the fact that the Copyright Act has extended copyright to digital content almost compels domestic policymakers to reflect upon their approach to TPMs, provided they seek to strike a sustainable balance between the owners of copyright and its users. The strengthening of copyright holders' rights through better enforcement, and the more appropriate tailoring of copyright exceptions to the digital environment, as suggested above, would remain very limited in their usefulness if there were no clarity, under national law, with respect to cases where TPMs are used by rights holders to block access to information or textbooks that would normally be authorized under copyright exceptions, and where specifically crafted limitations and exceptions could be waived under electronic access contracts.

In this context, it is important to consider to what extent the WIPO Internet Treaties could offer any useful guidance. The WCT and the WPPT provide an obligation for parties to:

> … provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that are used by authors [or by performers or producers of phonograms] in connection with the exercise of rights under this Treaty or the Berne Convention and that restrict acts, in respect of their works, which are **not** authorized by the authors [or by performers or producers of phonograms] concerned **or permitted by law**.[375] (emphasis added).

The WCT and WPPT leave countries free to limit their support of effective TPMs (i.e. through anti-circumvention legislation) to cases where the intended third party act is not permitted by domestic law. In other words, countries may refuse to support effective TPMs where the latter restrict uses that are permitted under a domestic copyright exception, even against the consent of the right holder. In addition, nothing prevents WTO members from providing in their domestic laws that all copyright limitations and exceptions are peremptory, mandatory and non-waivable, thus addressing concerns about the effects of unilateral electronic access contracts that impose waivers of statutory copyright limitations and exceptions.[376]

While many OECD countries have taken a fairly restrictive approach in their domestic implementation of the WIPO Internet Treaties by broadly supporting the use of TPMs to prevent many third party uses not authorized by the right holder (as opposed to uses not permitted under domestic law),[377] a proposal in the literature builds upon the freedom of WCT and WPPT parties to limit support of TPMs to cases where the intended third party act is not permitted by domestic law.[378] In cases where TPMs restrict fair uses of copyright, such as those under the Ugandan teaching or library exception, this view suggests enabling the user, either through domestic legislation or case law, to notify the right holder of the intended fair use and request the right holder to take down the TPM as far as it blocks that specific use. As expressed by Reichman *et al.* (2007):

> On this approach, any confrontation between the user community's efforts to make non-infringing uses of … material available to the public on a website and the copyright owners' technological fencing … could elicit a demand from the non-infringing user group for a right to limited decryption for purposes of indexing the material in question and extracting specified components in order to complete a specified non-infringing project. Copyright owners could be given 14 days either to deny the limited circumvention proposal or to allow it by silence, without prejudice. In case of denial, the user group would be entitled to seek a declaratory judgment vindicating or denying its claim to circumvention for the purpose of the specified non-infringing uses.[379]

The advantage of this approach is, above all, its preservation of fair uses of copyrighted material in the digital environment, providing a tool against the abuse of TPMs by rights holders. The obvious downside is its "palpable transaction costs at the outset",[380] especially in a developing country context. Implementation of this regime requires a judiciary that is experienced in distinguishing copyright infringing and non-infringing uses. In addition, financial resources would be needed to bring TPM challenges. Both issues may be addressed, in part, by requesting financial and technical assistance from public interest organizations that have a stake in the unfettered use of copyright limitations and exceptions in the digital environment.[381] This being said, it seems difficult to assess to what extent such a regime would be workable in Uganda. Before making any final recommendations in this regard, it is suggested that the issue be subjected to a consultative process among domestic stakeholders.

4.9 Copyright exceptions and computer software

While computer software has to be protected as literary works under the TRIPS Agreement and the Berne Convention, 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. Discovering the software concept may offer useful guidance in the independent creation of competing or interoperable software. A number of important copyright-related problems arise in this context, the treatment of which would go beyond the scope of this report. Suffice it to say here that the Copyright Act lacks any provision on the extent to which the reverse engineering of computer software is authorized, as an expression of the fundamental 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."). Considering the importance Uganda has been attaching to its ICT sector, there seems to be an urgent need for legislative reform in this regard, with a view to providing legal predictability to software developers.

4.10 **Parallel importation of copyrighted textbooks** (Section 32(1)(a) of the Copyright Act)

Reference is made to the section on parallel importation in chapter II of this report. 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.[382] 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. This would, however, only be feasible if Uganda allowed for the parallel importation of copyrighted materials into the country. As already observed in chapter II of this report, the current Copyright Act does not seem to provide for this. Section 32(1)(a) of the Act states that "infringement of copyright or neighbouring rights occurs where, without a valid … authorization … a person deals with any work or performance contrary to the permitted free use and in particular where the person does or causes or permits another person to … **import into Uganda** otherwise than for his or her own private use …" . (emphasis added)

This provision qualifies any imports into Uganda as copyright infringements, without specifying that no infringement will take place if the copyrighted work before being imported into Uganda has already been marketed in a foreign country by the copyright holder or with his consent. Without such a clarification, the above provision must be interpreted as implying a rule of national copyright exhaustion, i.e. where the right to distribute the copyrighted work is only exhausted upon the first sale of the protected item on the national market of Uganda. While this may be in the interest of copyright holders, who can prevent lower priced importations of their own textbooks, it does limit the government's freedom to procure cheaper textbooks abroad, to the extent the latter are actually sold at cheaper prices than in Uganda. With a view to promoting access to textbooks, the government may want to

consider introducing a rule of international copyright exhaustion, which would enable the government or any third party to procure copyrighted textbooks anywhere in the world where these are available at low prices. Alternatively, the government could consider introducing a rule of regional copyright exhaustion, thus enabling parallel imports from a certain region, such as the EAC, while sheltering domestic copyright holders from parallel imports from other countries.

5. Summing up: Main recommendations

5.1 General considerations

- Overall, the Copyright Act contains detailed provisions on the rights of holders of copyright and neighbouring rights, including in the digital environment, while its provisions on exceptions to copyright are rather vague and do not sufficiently address digital content;
- In order to strike a fair balance between the interests of copyright holders and users of textbooks, it appears essential to tailor the available copyright exceptions to the realities on the ground, i.e. the widespread inability of students to pay for original, hard copy textbooks, and the question of how to take advantage of the electronic dissemination of content, while ensuring creators receive a fair amount of revenue;
- At the same time, it is equally important to improve copyright enforcement, in particular through awareness raising among rights holders and capacity-building among enforcement authorities.

5.2 Copyright policy and law

Recommendation no. 24: Provide for training and capacity-building on copyright enforcement

- The government should undertake serious efforts in training and building capacities of copyright owners, lawyers, state authorities and the judiciary in the enforcement of copyright.
    - Right holders need to understand their primary responsibility for the initiation of copyright enforcement proceedings;
    - The judiciary, the customs authorities and the police need to have the capacity to respond to rights holders' requests;
    - There should also be capacity-building activities for URSB staff with respect to both copyright enforcement and inspection of collecting societies, and possibly an increase in the number of staff charged with these responsibilities;
    - Technical and financial support for these activities should be requested from OECD countries. WIPO could also be approached in this respect;
- The public should be sensitized for the potential benefits of a well-balanced copyright law for the promotion of domestic artists.

This being said, however, the government should ensure a revision of the Copyright Act to include more flexible and appropriate provisions on copyright exceptions. Merely enforcing the Copyright Act in its 2006 version will likely aggravate access to textbooks problems in Uganda.

Recommendation no. 25: Promote the use of open source/Creative Commons licences

- Publishers are strongly encouraged to use open source licences, 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 licence should be made in close consultation with the Ministry of Education;

- Publishers should promote the urgent development of a national Creative Commons licence.

Recommendation no. 26 (a): Provide for clearer language in the provisions on copyright exceptions (here: the teaching exception)

- Instead of reproducing the vague language used under article 10(2) of the Berne Convention ("use by way of illustration in a publication", etc.), the Copyright Act (section 15(1)(c)) should more clearly refer to "reproduction" of copyrighted materials, including digital copies;
- The teaching exception should directly authorize the reproduction, to a certain extent, of teaching materials (inter alia, textbooks) by the students themselves;
- Authorizing students to make copies themselves should not entitle them to make further copies of the work and to disseminate them beyond the context of the teaching institution. This would be a decision to be made by the rights holder (author) or publisher of the textbook. Digital copies produced at schools, while accessible for free to enrolled students, could be made to contain software that allows just one reproduction process, thus preventing further electronic dissemination.

Recommendation no. 27 (a): Provide for more flexible criteria to define the extent to which a textbook may be copied under the exceptions (here: the teaching exception)

- The extent to which a textbook may be reproduced in the context of the teaching exception (through a first digital or a reprographic copy) should be determined not only on the basis of the fair use criteria (enumerated under section 15(2) of the Copyright Act), but also on the basis of criteria of affordability and availability (as for example in Australian copyright law). In addition, 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;
- Provided this constitutes the ultimate means for students to find access to needed textbooks, even the reproduction (through a first digital or a reprographic copy) of major parts of a textbook could be justified. This would not apply where:
    - The subject matter of the class only requires the reproduction of certain chapters of the book (e.g. a science class as opposed to an English literature class);
    - The publishers are willing to make available to schools full electronic copies of textbooks, and schools are actually able to provide Internet access to their students. These publishers could be rewarded through the grant of a purchase agreement with the government for a specified number of textbooks, meeting the students' needs. Procurement regulations would have to be amended accordingly, adding the availability of online versions of textbooks as a new selection criterion, taking account of actual Internet connectivity in educational institutions;
    - Secondary and tertiary education students should be made aware of available online versions of textbooks and should be subject to a university code of conduct to abstain from making full copies or copies of major parts of textbooks in those cases. Such a code could also inform students about the requirement to limit copying activities to those parts of the book absolutely needed to follow classes. Continuous disrespect of such a code of conduct could be sanctioned by the university, amounting up to fines and, for repeated transgressions, the cancellation of the student's enrolment;
    - To the extent that copies may be made, according to the guidelines above, it is suggested that the law provide for an obligation by the owners of photocopy machines to pay a levy to the right holder or the publisher, ideally represented by an accountable collecting society. Such levies could be funded from a

generally applicable flat rate on photocopies, to be collected from users. Such a flat rate, however, would have to take account of users' ability to pay.

Recommendation no. 26 (b): Provide for clearer language in the provisions on copyright exceptions (here: the libraries and educational institutes exception)

- The reference in the libraries and educational institutes exception (section 15(1)(j)(ii) of the Copyright Act) to the "**right** of the author of the work" (emphasis supplied) arguably neglects the balance needed between the interests of rights holders and larger public interests, such as access to information. In order to accommodate such a balance, the above reference should be replaced by a reference to the "**interests** of the author of the work", and by adding 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";
- The larger public interest may be invoked to justify the authorization of libraries/educational institutes to make available copies of protected works to their users. However, this does not authorize the user to make further electronic copies of the work and to disseminate them further. This would be a decision to be made by the rights holder (author) or publisher of the textbook. Technological protection measures may be used by the educational institution/library to prevent further dissemination by users of digital content.

Recommendation no. 27 (b): Provide for more flexible criteria to define the extent to which a textbook may be copied under the exceptions (here: the libraries and educational institutes exception)

The objective of the libraries and educational institutes exception (section 15 (1)(j) of the Copyright Act) is comparable to that of the teaching exception, i.e. to enable users' access to needed (teaching) materials. As opposed to the teaching exception, which should authorize students directly, a distinction needs to be made between reproduction by the educational institution/library to provide users with access, and further reproduction activities by the users themselves.

- Textbooks and other works may be reproduced by the library or educational institute in hard copy or digital form and be made available to the user. 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 the textbooks available in electronic form and solely on school premises does not affect the overall purchase agreements between the government (or the schools) and the publisher on hard copy textbooks that students may take home;
- As to the admissible extent of reprographic copies made by the user, the same observations apply as under the teaching exception. In order to meet the requirements under the three-step test, elements such as affordability, availability, the subject matter of the class at issue and the payment by the teaching institutes or libraries of copying levies to the right holder have to be taken into account.

Recommendation no. 26 (c): Provide for clearer language in the provisions on copyright exceptions (here: the private personal use exception)

- For the purpose of clarity, it may be appropriate to substitute the reference in this provision (section 15 (1)(a) of the Copyright Act) to "production" with a reference to "reproduction", in line with the definitions provided under section 2 of the Copyright Act;
- As in the cases of the teaching and educational institutes/library exception, this exception does not comprise the authorization to make further electronic or paper copies (i.e. in addition to the first copy) and disseminate them. Digital copies made

available by the publisher could be made to contain software that allows just one reproduction process, thus preventing further electronic dissemination.

Recommendation no. 27 (c): Provide for more flexible criteria to define the extent to which a textbook may be copied under the exceptions (here: the private personal use exception)

- As to the extent to which textbooks may be copied, reference is made to the discussion of the teaching exception, as far as reprographic copies and the first reproduction of digital content are concerned. In order to meet the requirements under the three-step test, elements such as affordability, availability, the necessity of reproduction to follow an educational programme, and the payment by owners of photocopy machines of copying levies to the right holder have to be taken into account.

Recommendation no. 28: Implement the WIPO provisions on the use of TPMs

The Ugandan Copyright Act has extended copyright to include digital content. The need for rights holders to use TPMs to shield digital content from unauthorized mass reproduction, as well as the need to monitor abuse of TPMs by rights holders (i.e. blocking access to information authorized under statutory copyright exceptions) make it desirable for Uganda to reflect upon possible approaches to the treatment of TPMs in relation to copyright exceptions.

- An option that leaves countries considerable flexibility to accommodate rights holders' and users' interests is the literal implementation of the language used in article 11 WCT and article 18 WPPT. Under such a provision, a country may refuse to support TPMs where the latter restrict uses of copyrighted materials that are permitted under a domestic copyright exception, even against the consent of the right holder;
- As a consequence, domestic legislation may provide users with the right to request the copyright holder to take down a TPM when it blocks a use of copyrighted material authorized under a domestic copyright exception. In case of denial, the user would be entitled to seek a declaratory judgment vindicating or denying its claim to circumvention for the purpose of the specified non-infringing uses (see above for details). 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;
- Another consequence of implementing the flexible provisions in the WIPO Internet Treaties (article 11 WCT and article 18 WPPT) would be the possibility to provide, in the Copyright Act, that all copyright limitations and exceptions are peremptory, mandatory and non-waivable, thus preventing rights holders from imposing upon users one-sided electronic access contracts waiving carefully crafted copyright limitations and exceptions.

Recommendation no. 29: Address the reverse engineering of software

The Copyright Act lacks any provision on the extent to which the reverse engineering of computer software is authorized, as an expression of the fundamental 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."). Considering the importance Uganda has been attaching to its ICT sector, there seems to be urgent need for legislative reform in this regard, with a view to providing legal predictability to software developers.

Recommendation no. 30: Authorize the parallel importation of copyrighted works

The Copyright Act (section 32(1)(a)) could be amended as follows.

- With a view to promoting access to textbooks, the government may want to consider introducing a rule of international copyright exhaustion, which would enable it to procure copyrighted textbooks anywhere in the world where these are available at low prices (see also Recommendation no. 19);
- Alternatively, the government could consider introducing a rule of regional copyright exhaustion, thus enabling parallel imports from a certain region, such as the East African Community, while sheltering domestic copyright holders from parallel imports from other countries.

Recommendation no. 31: The way forward

This report has sought to make recommendations that take account of the actual technology and knowledge situation in Uganda. In so doing, we have put much emphasis on the existence of a robust public domain to spur technological learning and incremental innovation. Our recommendations seek to strike a balance between various, and sometimes opposing, interests. Thus, our last recommendation is to establish an inter-ministerial body to consider carefully the recommendations in this report in open-ended consultations with domestic stakeholders and experts.

Notes

268 See UNDP (2008).
269 Ibid.
270 See Nannyonjo H (2007). Education inputs in Uganda: an analysis of factors influencing learning achievement in grade six. World Bank working paper no. 98, Africa Human Development Series. The World Bank: xiii.
271 Interview with Godfrey Arnold Dhatemwa, Commissioner, Education Planning Department, Ministry of Education and Sports, 14 May 2008.
272 Interview with Dr. Elisam Magara, Director, East African School of Library and Information Science, 16 May 2008; and interview with James Tumusiime, Group Managing Director, Fountain Publishing and Chairman, National Book Trust; interview with Ann Nambalirwa, Publications Officer, Fountain Publishing; and Charles Batambuze, Executive Secretary, National Book Trust, on 19 May 2008.
273 Interview with E. Magara. For more details, see section 3 of this chapter.
274 Interviews with E. Magara and G. A. Dhatemwa.
275 Interview with E. Magara, describing the preferences of Ugandan academics.
276 Interview with J. Tumusiime, A. Nambalirwa and C. Batambuze.
277 Ibid.
278 Interview with Hilda Twongyeirwe Rutagonya, Coordinator, FEMRITE (Uganda Women Writers' Association), 19 May 2008.
279 Interview with E. Magara.
280 For an overview of these trends, see Commission on IPRs (2002): 100. See also, more recently, Reichman JH and Okediji RL (2009). Empowering digitally integrated scientific research: the pivotal role of copyright law's limitations and exceptions.
281 See http://www.education.go.ug/.
282 See http://www.education.go.ug/strategicPlan.htm#Strategic per cent20Objectives.
283 For the cycle 2005–2007, see http://www.education.go.ug/textbooks_&_guides.htm.
284 ULRC (2004b). *A Study Report on Copyright and Neighbouring Rights Law* (Law Com Pub. No. 9 of 2004). Kampala: xix, footnote 5.
285 Available at http://www.ict.go.ug/policy.html (hereinafter ICT Policy).
286 Interview with Tom Buringuriza, Deputy Executive Director, Uganda Investment Authority, on 15 May 2008.
287 ICT Policy: 32 (Policy Statement and Vision).
288 Ibid.: 36, strategy (c)/Objective 6.
289 Ibid.: 39, strategy (c)/Objective 11.
290 Ibid.: 40: Objective 14 (Enhancement of Collaboration and Coordination at Local, Regional and International Levels) does not refer to education.
291 Telephone interview with David Turahi, Acting Director for Communications, ICT Ministry, 19 May 2008.
292 See section 4(1) of the Uganda Registration Services Bureau Act. See also above, in chapter I.
293 Interview with Juliet Nassuna and Maudah Atuzarirwe, URSB, 14 May 2008.
294 Interview with John Magezi, Magezi, Ibale & Co., Advocates, 15 May 2008.
295 Interview with J. Nassuna and M. Atuzarirwe.
296 Interview with Dr. Dick Kawooya, African Copyright and Access to Knowledge Project, 20 May 2009.

297 Interviews with Henry Haduli, Commercial Court, 14 May 2008 ; J. Magezi; E. Magara; J. Tumusiime, A. Nambalirwa and C. Batambuze; J. Wasula; H. Twongyeirwe Rutagonya.
298 Interview with H. Haduli.
299 Interview with E. Magara.
300 Interview with H. Haduli.
301 Uganda, as an LDC, is granted a transition period until 1 July 2013 for the general application of the TRIPS provisions (except the obligation to respect national and most favoured nation treatment). See WTO (2005). Uganda is also granted an additional transition period until 1 January 2016 for the implementation of the TRIPS provisions on patents and undisclosed information (including clinical test data) in the area of pharmaceutical products. See WTO (2002). For a more detailed analysis, see chapter II of this report.
302 See the list of approved textbooks and publishers for primary education by the Ministry of Education for the cycle 2005–2007 at http://www.education.go.ug/textbooks_&_guides.htm.
303 Interview with J. Wasula, according to whom musicians make most of their income from live concerts, rather than CD sales. The reason for this is the widespread piracy of CDs. Mr. Wasula acknowledged, however, that the distribution of CDs through pirates is much more efficient than through authorized channels.
304 According to J. Wasula, CISAC guidelines provide that publishers should not hold more than 50 per cent of a royalty payment, while the remaining 50 per cent should go to the creator. Interview with J. Wasula.
305 Interviews with J. Wasula and D. Kawooya.
306 Interview with D. Kawooya and e-mail communication from C. Batambuze, 26 May 2009.
307 World Bank 2007, p. 28. While on average, six pupils share one mathematics textbook at urban schools, the ratio at rural schools is one such textbook for 14 students (figures referring to sixth grade students).
308 Ibid.: 29.
309 Ibid.
310 Ibid.
311 Interview with E. Ongom.
312 See Ahimbisibwe F (2009). Uganda: education, publishers in dispute. http://allafrica.com/stories/200902130040.html.
313 Ibid.
314 Ibid.
315 Interview with E. Magara.
316 Ibid.
317 Ibid.
318 Interview with D. Kawooya.
319 Ibid.
320 Ibid.
321 See sections 57–78.
322 Interview with D. Kawooya.
323 Interview with J. Tumusiime, Group Managing Director, Fountain Publishing; and A. Nambalirwa, Publications Officer, Fountain Publishing.
324 Ibid.
325 Interviews with H. Twongyeirwe Rutagonya and D. Kawooya.
326 Interview with E. Magara; and interview with J. Tumusiime, A. Nambalirwa and C. Batambuze.
327 Interview with E. Magara.
328 Ibid.
329 Interview with J. Tumusiime, A. Nambalirwa and C. Batambuze.
330 Interview with E. Magara.
331 See http://www.idrc.ca/acacia/ev-117012-201-1-DO_TOPIC.html.
332 Interview with J. Tumusiime, A. Nambalirwa and C. Batambuze.
333 See http://www.fountainpublishers.co.ug/product_info.php/products_id/804.
334 For an overview of available national licenses, see http://creativecommons.org/international/.
335 For an overview of the steps required in such a "porting" process, see http://wiki.creativecommons.org/International_Overview.
336 See ICT Policy: 17, 25. Subscribers outside Kampala have to make "national" calls to connect to their ISP, which makes access very expensive.
337 Interview with D. Turahi.
338 ICT Policy: 23.
339 Ibid.
340 Interview with D. Kawooya.
341 Interview with T. Buringuriza.
342 See Rens A *et al.* (2006). Intellectual property, education and access to knowledge in Southern Africa. UNCTAD-ICTSD regional research paper. (http://www.iprsonline.org/unctadictsd/docs/06 per cent2005 per cent2031 per cent20tralac per cent20amended-pdf.pdf) (regarding the situation on Botswana, Lesotho, Namibia, South Africa and Swaziland).
343 For example, interviews with E. Wagara; with J. Tumusiime, A. Nambalirwa and C. Batambuze; and with J. Wasula.

[344] See Masinde J (2008). Artistes' body demands change in copyright law. http://allafrica.com/stories/200806090510.html.
[345] See ULRC (2004b): xviii.
[346] Ibid.: xxi–xxiii.
[347] Ibid.: xviii–xx.
[348] Ibid.: xix.
[349] Ibid.
[350] On the importance of distance learning classes in the African context see African Copyright and Access to Knowledge (ACA2K) (2009). Copyright and A2K in Africa: research findings on limitations and exceptions from eight-country study. Briefing paper 2. Paragraph 3.2.
[351] See preambles to the WCT and the WPPT.
[352] See Agreed Statement concerning Article 10 of the WCT, and Agreed Statement concerning Article 16 of the WPPT.
[353] See also Reichman and Okediji (2009).
[354] See page xix, highlighting as important considerations for lawmakers, inter alia: "copyright law amendments permitting the 'educational use of modern sources of information such as the Internet without infringing copyright'; and "whether new approaches to copyright would need to be developed for the digital environment".
[355] See Okediji R (2006). The international copyright system: limitations, exceptions, and public interest considerations for developing countries. Issue paper no. 15. UNCTAD-ICTSD. Geneva: 16, noting that so far, only 13 countries have made notifications regarding their potential use of the Berne Appendix.
[356] Reichman and Okediji (2009): 25.
[357] Available at http://www.wipo.int/clea/en/details.jsp?id=306.
[358] See article 40(2), (3) of the Australian Copyright, Act (Consolidation), 27/06/1968 (30/07/2002), No. 63 (No. 63). This Act was amended to embrace the digital environment through the Copyright Amendment (Digital Agenda) Act 2000, No. 110, 2000. For that purpose, the original references to "copying" (i.e. the reprographic context) were replaced by references to "reproducing" (thus including digital copies). All documents are available at http://www.wipo.int/clea/en/details.jsp?id=306.
[359] Note that in other contexts, such as scientific research, both access to information and its subsequent dissemination among colleagues may be warranted to accommodate the needs of modern collaborative research. This would, however, go beyond the scope of this chapter, which focuses on access to learning materials.
[360] See http://www.ip.mpg.de/ww/en/pub/news/declaration_on_the_three_step_.cfm and http://www.ip.mpg.de/shared/data/pdf/declaration_three_steps.pdf (hereinafter Max Planck Declaration). Initiators and coordinators of the declaration include one director of the Max Planck Institute for Intellectual Property in Munich.
[361] It should be noted in this context that Uganda is not bound by the WTO Plurilateral Agreement on Government Procurement.
[362] See the interpretation of "reproduction" under section 2 of the Copyright Act.
[363] See section 49(5A) of the Australian Copyright, Act (Consolidation), 27/06/1968 (30/07/2002), No. 63 (No. 63).
[364] See WTO (2000a): para. 7.69. This view was confirmed in WTO (2005). Panel Report on *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs.* WT/DS174/R. 15 March. Para. 7.663.
[365] See WTO (2000b). Panel Report on *United States – Section 110(5) of the US Copyright Act.* WT/DS160/R. 15 June. Para. 6.227. While also applying a legal analysis under the first step, the copyright panel was more hesitant to expressly include "relevant public policies and other social norms" in its analysis of the third prong.
[366] Max Planck Declaration: 2.
[367] See preambles to the WCT and the WPPT.
[368] See, for instance, section 53(1) of the German Copyright Act.
[369] Note that in some countries, such as Germany, the private use exception does not under any circumstances permit the reproduction of the entirety of the work; see section 53(4)(b) of the German Copyright Act.
[370] See WIPO (2009). Draft report of the eighteenth session of the Standing Committee on Copyright and Related Rights. Geneva. May. Forthcoming at http://www.wipo.int/copyright/en/.
[371] See Penna FJ and Visser CJ (2002). Cultural industries and intellectual property rights. In: Bernard Hoekman *et al.*, eds. *Development, Trade and the WTO: A Handbook*. World Bank.
[372] See Reichman and Okediji (2009): 35–36.
[373] Ibid.: 28.
[374] See Agreed Statement concerning Article 10 of the WIPO WCT and Agreed Statement concerning Article 16 of the WIPO WPPT.
[375] See article 11 of the WCT and article 18 of the WPPT.
[376] See the proposal by the Max Planck Institute (2008). European Commission – Green paper: Copyright in the knowledge economy – comments by the Max Planck Institute for Intellectual Property, Competition and Tax Law. Max Planck Institute for Intellectual Property, Competition and Tax Law research paper series no. 08-05. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1317730 (last visited Apr. 29, 2009).

[377] See Reichman and Okediji (2009): 33 (criticizing the United States Digital Millennium Copyright Act/DMCA and the EU's Directive on the Information Society/Infosoc).

[378] Reichman JH *et al.* (2007). A reverse notice and takedown regime to enable public good uses of technically protected copyrighted works. Social Science Research Network (SSRN). http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1007817.

[379] Ibid.: 29.

[380] Ibid.

[381] Reichman *et al.* (2007) in this context refer to the Electronic Frontier Foundation and high technology clinics, such as the ones at American University, Boalt Hall, Stanford and USC Law Schools.

[382] E-mail communication from Charles Batambuze, 26 May 2009.