

GLOBAL TRADE, HEALTH AND ISSUES OF GENERIC MEDICINES FOR AFRICA

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AND DEVELOPMENT**

Kampala – Uganda

A modern Intellectual Property Battle in sixth century Ireland

- St. Columba was an Irish Gaelic missionary and one of the 12 Apostles of Ireland. Those twelve were saints who studied under St. Finian at Clonary Abbey;
- Columba was known for constant study and prayer- He is said to have written 300 books, by hand of course, continuing to transcribe up to the night before he died.
- Finian and Columba got into a disagreement over a psalter;
- Columba borrowed the manuscript from Finian--without permission--secretly copied it with the intention of keeping it for his own use.
- But Finian said no, **that this was theft--illegal copying! He demanded that Columba hand over the copy he had made;**

The Battle:

- Finian took the matter to King Diarmait mac Cerbhiall, the High King of Ireland, for arbitration.
- Believing he **had done nothing wrong** in his attempt to spread the word of the church, Columba agreed.
- Finian's argument was simple: My book. **You can't copy it. He felt that if anyone was going to copy it that it should be done through certain procedures and certainly not in secret under his own roof.**
- Columba's response was **-that the book had not suffered by his copying. "It is not right,"** he said, **"that the divine words in that book should perish, or that I or any other should be hindered from writing them or reading them or spreading them among the tribes."**

The Battle:

- In his closing address, he told the court **that those who owned the knowledge through books were obligated to spread the knowledge by copying and sharing them.**
- He felt that **to not share knowledge was a far greater offense than to copy a book that lost nothing by being copied.**



How would you Decide this case?

The Decision:

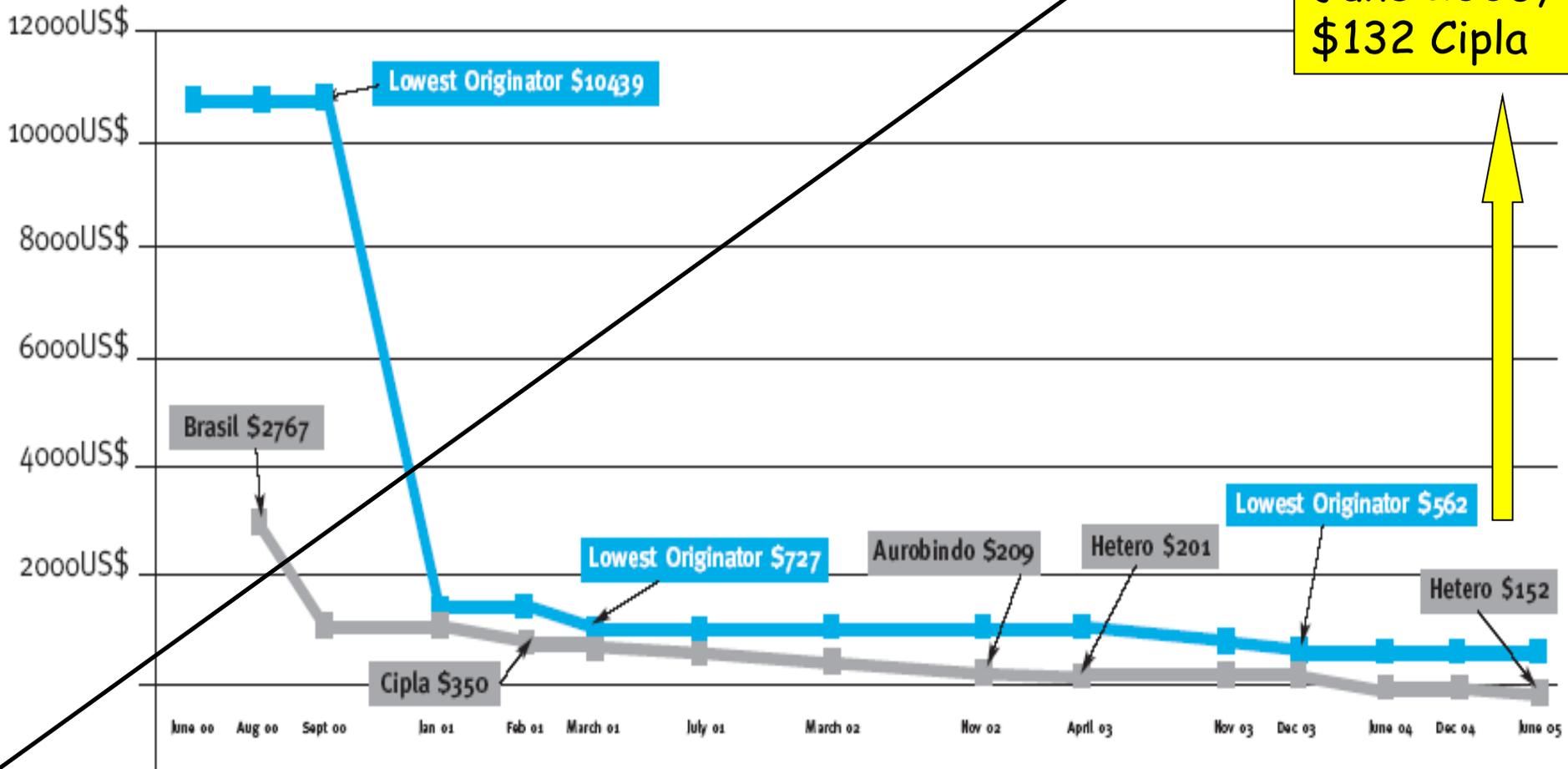
- But the king ruled in Finian's favor, famously saying, "**To every cow belongs its calf; to every book its copy.**" In other words, every copy of a book belonged to the owner of the original book.
- Of course, the story didn't end there. After more arguing and Columba's next offense, the result was the **Battle of Cúl Dreimhne**, the death of 3,000 people, and Columba's exile.

Accessing Medicines:

- From **40,000 people** in LMICs in 2000 to **over 5 million people** having access ten years later (UNDP, 2010);
- This success has been directly linked to the **drastic fall in the price of these drugs**;
- In 2009, **90%** of the ARVs delivered by the programs of the US President's Emergency Plan for AIDS Relief (PEPFAR) were **generic**
- The cost of first generation ARVs from over **10,000 US dollars** to **67 dollars** per person per year (UNDP, 2010);;
- Thanks to the **competition from generic manufacturers**;

Effects of Generic Competition on ARV Prices

May 2000-June 2005



June 2006,
\$132 Cipla

Current Demands:

- **Only 3rd of the people** who need treatment have access to it.
- In low-income countries **50–90%** of the money people spend on health goes toward buying medicines (UNDP, 2010);
- An **increased demand** as people on treatment live longer
- **Resistance** to 1st generation treatment regimes often requires patients to switch to more expensive **patent-protected** 2nd and 3rd line therapy;
- The high cost of patented pharmaceuticals for **treatment of co-infections** such as tuberculosis, or hepatitis C
- The recommendation of the WHO to **commence antiretroviral therapy earlier**, which will increase the number of people requiring treatment.

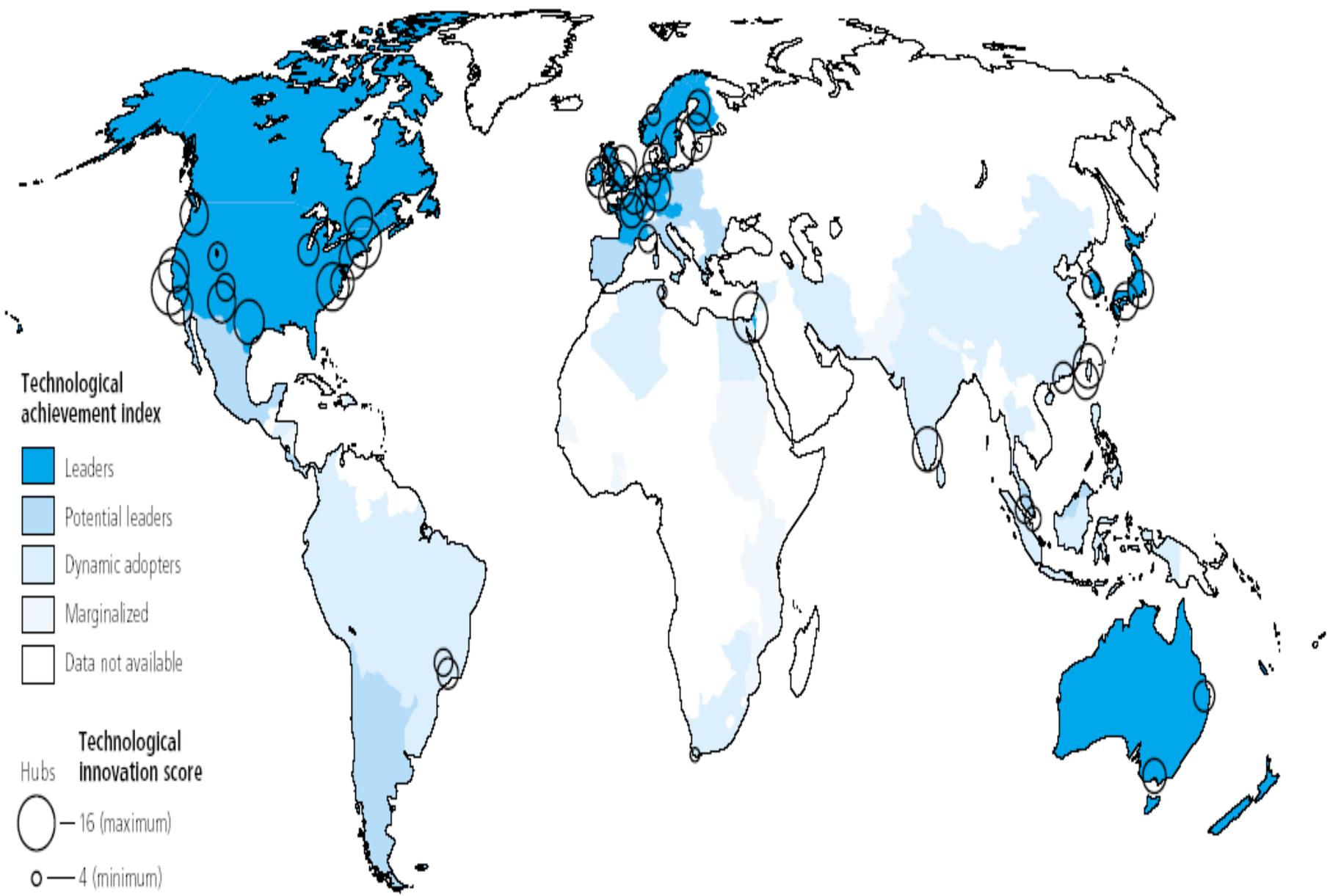
Access to Medicines Index 2018

- Globally, **two billion people** cannot access the medicine they need (**Price??**);
- Pharmaceutical companies are getting **more sophisticated** in how they get essential products to poor people;
- **Cancer incidence** continues to rise in low- and middle-income countries;
- Access to pharmaceuticals is better guaranteed through models such as **equitable pricing or licensing than through donations**.



While there are a range of factors that contribute to the prices of medicines, one of the more significant ones is Intellectual Property Protection (IPRs)

THE GEOGRAPHY OF TECHNOLOGICAL INNOVATION AND ACHIEVEMENT



Intellectual Property: A Basic Introduction

- Refers to a bundle of rights awarded by society to individuals or organisations over creative works: inventions, literary and artistic works and symbols, names, images, designs as a bargain that the outcomes of the rights will benefit society at large.
- Gives the creator the right to prevent others from making unauthorised use of their property for a limited period
- Generally can be categorised as follows:
 - Industrial Property (functional commercial innovations),
 - Patents, Industrial designs, Trademarks, Geographical Indications, Trade Secrets, Geographical Indications
 - Artistic and Literary Property (cultural creations)
 - Copyright
 - Sui Generis Systems
 - Integrated Computer Circuits
 - Plant Breeders' rights

Patent:

- An exclusive right awarded to an inventor to prevent others from **making, selling, distributing, importing or using their invention, without license or authorization from the patent holder;** **(PRODUCT AND PROCESS)**
- This is for a fixed period of time - TRIPS stipulates **at least 20 years of protection;**
- There are three requirements that determine the patentability of an invention: **Novelty** (not “prior art”), **Inventive step** (not obvious to one skilled in the field), and **Industrial applicability**.

The TRIPS Agreement (Trade Related Aspects of Intellectual Property Rights)

- First multilateral agreement prescribing minimum standards...all countries have to harmonise to these standards...except **LDCs** that have transitional period until 2021 (2033 pharmaceuticals) - which can be further extended
- The TRIPS Agreement prescribes minimum standards for patent, copyright and related rights, trademarks, geographical indications, industrial designs, layout-designs of integrated circuits, protection of undisclosed information, enforcement of IPRs etc.

Origins of TRIPS:

- During the Uruguay Round (that led to the establishment of the WTO), **developing countries that participated in the TRIPS debate resisted the incorporation TRIPS are part of the WTO** as WTO is essentially about free trade, while IP is a protectionist instrument of developed countries.
- However, as a result of strong multinational lobby (esp the pharmaceutical industry), persistence of developed countries, and as part of a larger package of trade-offs, TRIPS was retained as part of WTO.
- But **developing countries fought very hard for flexibilities** to be able to develop IP policies suitable for level of development

The theory Informing the Resistance:

- In the **early stages of development....the now advanced countries:**
 - **did not provide for adequate protection of IP rights** of foreign citizens
- e.g. most countries including **Britain, Netherlands, Austria, France...allowed their nationals to patent imported inventions** (lax on originality requirement)
- **Switzerland** had no patent law until 1888 and thereafter **did not grant patents** for chemical inventions **since they were copying a lot of chemical and pharmaceutical** technologies from Germany, which was a world leader then.
- **Dutch abolished their patent law in 1869 which then allowed Phillips, to produce light bulbs based on the patents “borrowed”** from the American inventor, Thomas Edison.
- US while it was in the process of developing **refused to protect foreigners’ copyrights since it was a net importer of copyright materials**

“.....when they were backward themselves in terms of knowledge, all of today’s rich countries blithely violated other people’s patents, trademarks and copyrights. The Swiss “borrowed” German chemical inventions, while the Germans “borrowed” English trademarks” and the Americans “borrowed” British copyrighted materials – all without paying what would today be considered “just” compensation”.

(Ha-Joon Chang, (2007) *Bad Samaritans: The Guilty Secrets of Rich Nations & the Threat to Global Prosperity*).

IP Statistics

- In 2001, **less than 1% of US patents were granted to applicants from developing countries**, nearly 60% of which were from seven of the more technologically advanced developing countries
- In 2006, **18 countries were considered intensive users**, (i.e. had more than 1000 Patent Cooperation Treaty (PCT) filings) **making up 94.8% of the patent filings. Aside from China, these were OECD countries.**
- In 2007, **more than 60% of the PCT filings** originated from the US, Japan and Germany.
- In **developing countries and LDCs**, most **patent holders are foreigners** which means what is being protected is foreign owned property. For example, 91% of patents granted in Malaysia in 2008 were to foreigners and this trend has been constant.
- **Between 1991 and 2004 only 20 patents were granted to applicants from LDCs** (compared to 1.8 million patents granted to developed countries)

IP, Growth and Innovation

- little evidence that strong IP rights encourages greater R&D in developing countries

e.g. Switzerland...in the late 19th Century....although no patent law...Swiss were the most innovative in this period. During this period, Swiss made world famous inventions in areas like textile machinery, steam engine, food processing milk etc.

- **UK Commission on IP & Development:**

*“We conclude that in most low income countries, with weak scientific and technological infrastructure, IP protection at the levels mandated by TRIPS is not a significant determinant of growth. On the contrary, **rapid growth is more often associated with weaker IP protection.** In technologically advanced developing countries, there is some evidence that **IP protection becomes important at a stage of development but that stage is no until a country is well into the category of upper middle income developing countries**”*

IP & Foreign Direct Investment

UK Commission on IP & Development:

- “The evidence that foreign investment is positively associated with IP protection in most developing countries is lacking”
- What is clear from the literature is that strong IP rights alone provide neither the necessary nor sufficient incentives for firms to invest in particular countries.
- If this was the case, then large countries with high growth rates but weak IPR regimes would not have received large foreign investment inflows in the past and even now e.g. China, India, Malaysia
- FDI usually depends on other factors e.g. stability, incentives such as tax breaks, local capacity, operating costs.
- In fact, high levels of IPRs protection **may lead title-holders to prefer the exportation of the final product rather than investment in or the transfer of technology to a foreign country** as the main channel for exploitation of their intellectual assets. IPRs may, hence, deter rather than foster technological catch-up and industrial development.

Report of the Commission on Intellectual Property Rights

- Whether IPRs are a good or bad thing, the developed world has come to an accommodation with them over a long period.
- Even if their disadvantages sometimes outweigh their advantages, by and large the developed world has the national economic strength and established legal mechanisms to overcome the problems so caused.
- Insofar as their benefits outweigh their disadvantages, the developed world has **the wealth and infrastructure** to take advantage of the opportunities provided.
- **It is likely that neither of these holds true for developing and least developed countries.**

SIR HUGH LADDIE, UK High Court Patents Judge

Lets Look at the TRIPS Agreement:

Preamble

*“Recognizing that intellectual property rights are **private rights**”*

*“Recognizing the underlying **public policy objectives** of national systems for the protection of intellectual property, including **developmental and technological objectives**”*

*“Recognizing also the **special needs of the least-developed country Members** in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to **create a sound and viable technological base**”*

Article 1 of TRIPS:

*“Members may but **shall not be obliged** to implement in their law more extensive protection than is required”. Further it states*

*“Members **shall be free to determine the appropriate method of implementing** the provisions of this Agreement within their own legal system and practice”. In short it is up to Member states to decide how to implement the provisions of this Agreement.*

TRIPS Cont

Article 7 – Objectives of IP

“The **protection and enforcement of intellectual property rights** should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and **in a manner conducive to social and economic welfare, and to a balance of rights and obligations.**”

□ **Article 8 – Principles**

“Members **may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition**, and to promote the **public interest** in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement

Appropriate measures, provided that they are consistent with the provisions of this Agreement, **may be needed to prevent the abuse of IPRS by the right holders**”

Some Flexibilities in the TRIPS Agreement:

- No Obligation to **implement beyond TRIPS** (Art 1);
- **Parallel Importation** (Art 6);
- Freedom in formulating or amending **national legislation and regulations** (Art 8);
- Limited **exceptions** to the exclusive rights (Art 30)
- **Government use** order;
- **Compulsory** License;
- **Bolar Provision**
- Pre and Post **Opposition Procedures**
- Countries determine the **appropriate method** of implementation (Art 1);

The Status IP Laws in Uganda

- Uganda is a founding member of the WTO
- It signed the TRIPS Agreement **upon the establishment of the multilateral trade body in 1994.**
- As an LDC, Uganda has a transitional period extending to 2021 to implement the **general provisions of the TRIPS Agreement;**
- Until 2033 in the case of provisions relating to **pharmaceutical products.**
- In the year 2000, ULRC led the process of reforming Uganda's commercial legislation.
- The ULRC commissioned a study to seek views on issues pertaining to the implementation of the WTO Agreement

ULRC sought views on:

- the **rights and obligations** of the Government under the various WTO Agreements;
- the goals to be pursued by the Government to **ensure benefits from the Agreements;** and
- Identification of the **best approach to legal implementation,** including identification of relevant laws to be addressed in order of priority.

ULRC Studies

the ULRC Study Noted:

... that it was expedient to implement the entire Agreement on TRIPS for *political considerations* and in order to complete the *framework for promoting investment*.

... given the *serious doubts on whether protection of intellectual property in fact attracts technology and on the other hand the legal implications of the short-cut of copying existing technology*, there is need for more debate to ascertain the balance between the interests of right-holders and the development needs of Uganda.

- ULRC had a specific study entitled: A Study Report on Industrial Property Law (Patents, Industrial Designs Technovations and Utility Models)

... the reform of *intellectual property has to strike a balance between protecting and respecting the rights of industrial property holders particularly holders of patents, and public interest concerns particularly those on access to essential drugs for a least developed nation like Uganda which is affected by diseases like malaria and HIV/AIDS ...*

ULRC

- The Study Made recommendations for utilization of TRIPS flexibilities such as
 - Transitional period;
 - Parallel Importation;
 - Compulsory licenses
 - Bolar provisions;
 - Voluntary licenses;

- The study noted, that protection of plant varieties would give plant breeders economic value, thus attracting the same treatment as the other commercial services under the IPR.

As a result of these reforms a number of laws and Bills are in place:

- The Copy Right and Neighbouring Rights Act (Seen as not part of the reform)
- The Industrial Properties Act
- Trademarks Act
- Plant Variety Protection Act
- Trade Secrets Protection Act, 2009
- Geographical Indications Act
- Competitions Bill of 2004, and
- Anti-counterfeiting Bill of 2009 (initially not part of the process)

Policy Space in the Current Laws:

- **The industrial property act:**
- **S. 101 (15)** - The rights accruing from patents for pharmaceutical processes shall not be enforceable until January 1, 2016, or such other period as may be granted to Uganda or least developed countries by the council;
- **S. 43 (1)** - The rights under the patent extend only to acts which are done for industrial or commercial purposes but do not extend to acts which are done for scientific research;
- **S.43 (2)** - 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.
-
- **S.58** - After the expiration of four years from the filing date of an application or three years from the grant of a patent, whichever last expires, a person may apply to the Minister for a licence to exploit the patented invention on the grounds that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Uganda.
- S.44 (e) - It is not an infringement of a patent ...to manufacture and export to another country a patented healthcare invention where the export of the invention addresses a health need identified by the other country

Some Developments in IP Policy

National Intellectual Property Policy

- ▣ Strengthen the institutional and legal frameworks for the administration and management of IP rights in Uganda
- ▣ Strengthen institutional, human resources and policy to enhance generation, protection and commercialization of IP rights by universities, research organizations and SMEs
- ▣ Strengthen institutional and human capacities for the enforcement of IP rights in Uganda
- ▣ Promote IP Training and Education

▣ **Key Concerns though:**

- ▣ Lack of regulations to implement Industrial Property Act 2014, Plant Varieties Act, 2014 and Geographical Indications Act, 2013.
- ▣ Need to review the copyright act, 2006 to take care of emerging issues
- ▣ Lack of policy or legislation on Traditional Knowledge

Ongoing Litigations :

CEHURD & Others Vs AG

- Whether the passing of the Plant Variety Protection Act 2014 without determining whether there was a requisite quorum was inconsistent with and in contravention of Articles 2(1) & (2), 88 and 94 (1) of the Constitution of the Republic of Uganda and Rule 23 of the Parliamentary Rules of Procedure?
- Whether the enactment of the Plant Variety Protection Act, 2014 without the participation of the communities to be affected by the Act was inconsistent with and in contravention of Principle XIV of the National Objectives and Directive Principles of State Policy and Article 8A and 38 of the Constitution?
- Whether sections 13(a) and (b) and section 15 (a), (b), (c) and (e) of the Plant Variety Protection Act, 2014 are inconsistent with the Principle of exhaustion of the rights and the right to property under Article 26 of the Constitution of Uganda.
- Whether the Petitioners are entitled to the declarations sought?

B.A.T Vs AG and CEHURD

- Whether Section 15(2) of the TCA contravenes and is inconsistent with Articles 40(2), 26 and 29(1) (a) of the Constitution? (65% health warning)
- Whether Section 16(3) of the TCA contravenes and is inconsistent with Articles 40(2), 26(1) and 29(1) (a) of the Constitution? – (Display at point of sale)

Other Frameworks:

The competition Bill section 43 (6) b

*The prohibition of certain anticompetitive agreements **does not restrict the right of any person to restrain any infringement of intellectual property rights** granted in Uganda or to impose such reasonable conditions as may be necessary for the purposes of protecting or exploiting such intellectual rights.*

Art. 51 (footnote 14): "counterfeit trademark goods" shall mean any goods, including packaging, bearing **without authorization** a trademark which is **identical to the trademark validly registered** in respect of such goods, **or which cannot be distinguished in its essential aspects** from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation

- EAC Regional Intellectual Property Policy on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, 2010
- The EAC HIV/AIDS Act

Key Messages!!

- Relationship between IP & Innovation and IP & Development is complex!!
- Strong IP protection and enforcement does not necessarily mean increase in innovation or technology transfer or foreign direct investment.
- In fact depending on the circumstance opposite may be true!!
- For developing and LDCs there is a high cost of strong IP protection and enforcement...because of access problems.
- As LDC, there is need to continue utilizing the Policy space provided by the flexibilities if we are to ensure medicines



THANK YOU