Uganda's Industrial Property Bill (2009) can achieve the traditional balance in intellectual property legislation

Uganda's Industrial Property Bill (2009) needs to be reviewed before it is enacted into law, to make full and maximum use of the flexibilities available in the TRIPS Agreement in order to guarantee public health, particularly access to essential medicines, for all Ugandans

THE INTELLECTUAL PROPERTY REFORM PROCESS IN UGANDA

THE CONCERN AROUND IPR LEGISLATION IS:

...high levels of protection can block access to new knowledge, promote monopoly, limit production, keep prices high and restrict access to new products.

THE UN World Intellectual Property Organisation (WIPO) defines intellectual property (IP) as the creations of the mind, such as inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. Government authorities grant IP rights (IPRs), in principle, to reward creators for originating the idea and to enable them benefit from their effort. The underlying aim is to motivate people to produce new ideas and encourage them to disclose their inventions.

IPRs are set out in national laws and protected through the traditional enforcement mechanisms of national laws and legal processes. However, after the founding of the World Trade Organisation (WTO) in 1994, the protection and enforcement of IPRs assumed a global dimension. The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) compels all member countries, including Uganda, to protect IPRs in all fields. Non-compliance is subject to the WTO's dispute settlement mechanism, which may – in the worst case – lead to trade sanctions.

As a least developed country (LDC), Uganda has a transitional period extending to 2013 to implement the general provisions of the TRIPS Agreement, and until 2016 in the case of provisions relating to pharmaceutical products. In preparation for full implementation, the country is in the process of reviewing its commercial laws to align them with the TRIPS Agreement. As a result, the Copyright and Neighbouring Rights Act and the Trademark Act were enacted in 2006 and 2010, respectively.

Other draft laws presently in the legislative process include: Industrial Properties Bill; Plant Variety Protection Bill; Trade Secrets Bill; Geographical Indications Bill; Competition Bill; and Counterfeit Goods Bill. The Industrial Properties Bill (2009), which addresses industrial property (inventions, trademarks, industrial designs, etc), is the proposed legislation that directly relates to access to essential medicines.

Hence is strong protection extended on all categories of products, it could hurt technological progress, public health, education, food security, environmental protection, etc (HEPS, 2010). Therefore, IPR legislation have traditionally sought to balance rewards to creators of new ideas with access to the benefits of those ideas by the general society.

It is possible for any country to protect intellectual property rights in a way that promotes creation and access to new technology, medicines, educational materials, etc. India, for instance, was able to avail generic versions of newly developed medicines relatively quicker by limiting medicine patents to only processes (leaving out the products). This encouraged local manufacturers to "invent around" existing patents to produce medicines using processes other than those used (and patented) by the originators (HEPS, 2010).

KIOS
THE FINNISH NGO FOUNDATION FOR HUMAN RIGHTS
OSIEA

PUBLIC HEALTH SAFEGUARDS AND FLEXIBILITIES IN THE TRIPS AGREEMENT

DOHA DECLARATION ON TRIPS & PUBLIC HEALTH:

'...the TRIPS Agreement does not and should not prevent members from taking measures to protect public health...'

Due to concerns that strong IPR protection was restricting access to essential medicines, WTO member countries agreed in 2001 that "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health... we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all" (WTO, 2001).

Hence, the Doha Declaration on TRIPS and Public Health of 2001 introduced a set of public health safeguards – better known as flexibilities – in the TRIPS Agreement, puttingpublic health before commercial interests (HOEN, 2003). The main public health flexibilities in the TRIPS Agreement are:

- **Government use:** This provision gives governments the right to use a patented invention without the authority of the patent holder for public, non-commercial purposes, e.g. public sector production of generic medicines, or import of generic versions of medicines for use in public hospitals.

- **Compulsory licensing:** The TRIPS Agreement allows governments to issue a license to use a patented invention without seeking the permission of the patent holder in situations of national emergency, extreme urgency, public non-commercial use, and similar situations. It is important to note that TRIPS does not limit the grounds or reasons for issuing a compulsory license. However, it requires adequate compensation for the patent holder and the holder of the compulsory licence produces strictly for the domestic market.

- **Parallel importation:** It is common to find a patent holder selling a drug at substantially different prices in different countries. The parallel importation provision gives governments the right to licence the importation of the drug from the country where is cheaper.

- **Bolar provision:** The "Bolar provision" allows competitors to prepare to produce a patented drug even before a patent actually expires. This may include testing and processing regulatory approval so that they are ready to start production as soon as the patent expires. This helps to bring in post-patent competition faster.

- The TRIPS Agreement only sets the minimum standards for the protection of IPRs. There is no obligation for member countries to implement more extensive protection than the minimum required by the TRIPS Agreement (Article 1).

- Member countries are free to determine the appropriate method of implementing the provisions of the TRIPS Agreement within their own legal systems and practice (Article 1)

- **Transitional Arrangements:** Due to their special social economic constraints, it was realised during TRIPS negotiations that LDCs like Uganda needed more time to build the capacity needed to benefit from a strong IP protection system. So they have been given an extended grace period until 2013 to comply with Trips obligations and in the case of medicine, LDCs are not obliged to grant or enforce patents on medicine until 2016 with a possibility of further extension if those constraints persist.

- **The right of governments to take measures to protect public health** and, in particular, to promote access to medicines for all. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The minimum IP protection standards and flexibilities have to be incorporated into the draft national legislation, the Industrial Property Bill (2009), whose drafting process started way back in 2000 and lapsed with the previous parliament, and passed into law before the 2016 WTO deadline for enforcement of patents.

TRIPS FLEXIBILITIES IN UGANDA'S INDUSTRIAL PROPERTY BILL (2009)

MBOI E. MISATI (6TH OCTOBER 2010):

...any obligations other than is provided for in the WTO-TRIPS is TRIPS-plus obligations.

The bill incorporates major aspects of the TRIPS flexibilities for access to medicines, such as the transitional period, bolar provision, compulsory licensing, voluntary licences, and parallel importation. However, the bill also has crucial gaps which if not addressed, are likely to prejudice Uganda's interventions in making medicines affordable and accessible for most Ugandans after the 2016 patents enforcement deadline.

- The bill makes provision for the LDC transition periods. However, it does not provide for any extension that may be sought and granted by the TRIPS Council. Leaving it at 2016 may mean that the Parliament will have to first amend the law in case there is further extension. The bill should expressly provide under section 8 (3) that pharmaceutical products are excluded from patent protection until 1st January 2016 or such other date as may be extended in the future. The bill should under section 28 (13) and (14) indicate that applications for pharmaceutical products should only be filled after 1st January 2016 or such other date as may be extended in the future.
- The Industrial Property Bill provides for bolar exception in a restrictive sense by restricting it to scientific research but not in case of acts done for industrial or commercial purposes.
- The bill should properly define the public emergency provision and indicate that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency;
- The conditions for grant of a compulsory license create barriers by requiring applications to go through the long court process. Compulsory licensing makes greater sense if the process of granting it is simple and expeditious. 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 of justice in consultation with the ministry of health should be authorised to issue the compulsory licence in the area of pharmaceuticals.
- 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;
- Section 60 of the bill makes a provision for government use. The main concern with this provision is that it subjects the government to consultation with the patent owner which may give the patent owner the opportunity to make objections thus failing the policy goal of the government. Such an obligation is not required under TRIPS. 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.

UGANDA'S IP-RELATED PUBLIC HEALTH CHALLENGES

ELLEN F. M. 'T HOEN (2003):

...the reasons for the lack of access to essential medicines are many, but in many cases the high prices of drugs are a barrier to needed treatments

Many Ugandans die of treatable illnesses for lack access to essential medicines. Availability of, and access to medicines continues to be a major problem (MOH 2010). Only 30 percent of the essential medicines and health supplies required for the basic package of healthcare are provided for in the national budget. Ministry of Health (2008) has found that even though more than two thirds (72 percent) of the households are close to a public health care facility, only one third believe that medicines are available in government health care facilities.

In Uganda, the main barrier to public access to essential medicines has two faces: while availability of medicines is poor in government health facilities, they are on average 3-5 times more expensive in the private sector, where the majority of people cannot afford them (MOH, 2008). A number of factors have been given for this catastrophe, with intellectual property protection, particularly patents, being a major contributor. Prohibitive drug prices are often the result of strong intellectual property protection (Hoen, 2003).

The Doha declaration (2001) on the TRIPS Agreement and public health also clearly noted that while IP protection may be important for the development of new medicines, it has negative effects on medicine prices and access. Governments in developing countries that attempt to bring the price of medicines down have come under pressure from industrialised countries and

the multinational pharmaceutical industry, demanding patent legislations that go beyond the obligations of TRIPS, a phenomenon often referred to as "TRIPS plus" (Hoen, 2003).

of and will remove a source of generic, innovative, quality drugs on which developing countries depend. It is unlikely that TRIPS will encourage adequate R&D in developing countries for diseases such as malaria and tuberculosis, because poor countries often do not provide sufficient profit potential to motivate R&D investment by the pharmaceutical industry, yet the enforcement WTO rules will have a negative effect on local manufacturing capacity (HOEn, 2003).

CONCLUSION

PUBLIC HEALTH FOCUS:

...the Industrial Property Act will serve Uganda's public health interests if it enables the country to increase the availability and affordability of medicines in the country

In reforming IP laws, Uganda as an LDC, is free to exploit any or all the flexibilities the TRIPS Agreement offers, and to adopt only the minimum levels of IPR protection that the Agreement requires. Only then, shall the country maximise public health benefits from the new IPR protection regime. As the bill stands, however, it contains unnecessary IPR protection over and above the minimum required by the TRIPS Agreement, and does not fully utilise flexibilities on the determination of national public health crises; the transition period; bolar provision; compulsory licensing; and others. Failure of the national legislation to utilise the flexibilities will mean costly wholesome enforcement.

The resulting Industrial Property Act should achieve Uganda's public health interests by aiming to: develop the capacity at national level for production of generic medicines; allow the widest possible scope for parallel importation; adopt a simple and expeditious procedure for compulsory licensing and government use order; allow extensive flexibility for scientific research and regulatory approval exceptions (bolar/early working provisions); and disallow data exclusivity, i.e. allow the submitted data to be relied upon by authorities in assessing and granting approvals for supply of medicines.

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For more information, contact:

CENTER FOR HEALTH, HUMAN RIGHTS AND DEVELOPMENT [CEHURD]
614 Tufnell Drive, Kamwokya; P.O Box 16617 Wandegeya, Kampala
Telephone: +256 414 532283; www.cehurd.org