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The Draft Industrial Property Bill (2007): Balancing inventor's rights with Public Health interests in Uganda's IP Legislation

By highlighting the proposed provisions of the Draft Industrial Property Bill (2007) that need to be reviewed to make full use of the flexibilities offered by the TRIPS Agreement, this paper shows how Uganda can balance the need to protect the rights of inventors with the common good of protecting public health, particularly access to affordable medicines by poor people

Background

Uganda is in the process of reforming its intellectual property (IP) laws not only to make them consistent with the multi-lateral Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) but also to facilitate greater access to affordable medicine and the growth of local manufacturing capabilities.

The TRIPS Agreement, which forms part of the agreement establishing the World Trade Organisation, sets the minimum standards for the protection of the rights of innovators to exploit their creations, which may be either industrial property (e.g. inventions, trademarks, industrial designs, etc); or copyrights (e.g. novels, songs, sculptures, etc). At the same time, the agreement provides for avenues for countries to design legislations that respond to their unique public health interests

In reforming their IP laws, least developed member countries like Uganda, are free to exploit those provisions in the TRIPS Agreement – popularly known as flexibilities – to design national IP laws that are tailored to national strategic interests. The Uganda Law Reform Commission (ULRC) has spearheaded the process of drafting a national IP law since 2000 and has so far improved the original version twice. However, the latest version, the Draft Industrial Property Bill (2007), which is now awaiting Cabinet approval before it goes to Parliament for enactment, still does not make full use of the TRIPS flexibilities.

Safeguards/Flexibilities in the TRIPS Agreement

Out of the realisation that strong patent protection has potential adverse impacts on access to medicine, the following flexibilities were built into the TRIPS Agreement during the negotiation:

- 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)
- Member countries are exempted from any legal action relating to parallel importation provisions (Article 6)

Pursuant to the objectives of the agreement (Article 7), member countries may ensure in national legislation that the protection and enforcement of intellectual property rights contributes to the promotion of technological innovation, technology transfer, mutual benefits for producers and users, and balance of rights and obligations.

In formulating or amending national legislation and regulations member countries are free to adopt measures necessary to protect public health and nutrition, and promote the public interest in sectors of vital importance to their development (Article 8)

Members are free to provide limited exceptions to the exclusive rights conferred by patents (Article 30) including use of the patented invention without the authorisation if the owner (article 31) such as compulsory licence and government use order.

Transitional Arrangements

Due to their special social economic constraints, it was realised during TRIPS negotiations that least developed countries (LDCs) like Uganda needed more time to build the capacity needed to benefit from a strong intellectual property 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 till 2016 with a possibility of further extension if those constraints persist.

What should be Uganda's Strategic Objectives for Public Health?

In terms of public health, the patent regime will serve Uganda's public health interests if it enables the country to increase the availability and affordability of medicines in the country. This may be achieved through:

- developing the capacity at national level for production of generic medicines;
- allowing the widest possible scope for parallel importation;
- adopting a simple and expeditious procedure for compulsory licensing and government use order;
- extensive flexibility for scientific research and regulatory approval exceptions (bolar/early working provisions); and
- disallowing data exclusivity i.e. allowing the submitted data to be relied upon by authorities in assessing and granting approvals for supply of medicines.

TRIPS Flexibilities that Need Improvement in the Draft Industrial Property Bill (2007)

1. Scientific research and regulatory approval exceptions

Sometimes referred to as "bolar provision", this exception allows governments to facilitate increased availability and affordability of drugs through early entry of generic versions into the market. The Draft Industrial Property Bill (2007) limits the exception only to scientific research and does not provide for acts done with a commercial intention such as securing regulatory approvals and registration which acts are considered to be for "industrial or commercial purposes".

Uganda's interest should be to use this exception to its fullest extent. Acts of commercial nature should be allowed to enable alternative producers enter the market as soon as the patent expires. But if on the other hand such procedures are done at the expiry of the patent, Uganda will be waiting for years to have generic medicines on the market. This delayed entry of cheaper products also means that the patent enjoys more years of monopoly while access to cheaper generic medicines remains elusive for the majority poor people. This provision is therefore Trips –plus and needs to be revised. We shall still be within the ambit of Trips provisions if we flex it a little further to allow acts done for commercial purposes provided that such purpose is not executed before expiry of the patent.

2. Compulsory Licensing

Under Article 31 of the TRIPS Agreement, member countries may make national laws that allow them to grant licences to other producers for the production of a patented medicine if the patent owner cannot

provide it at a reasonable price or in sufficient quantities. The draft Industrial Property Bill contains provisions on compulsory licensing, but the requirements and procedures create barriers in several ways:

a) Unrealistic demand for capacity guarantees

The person applying for the compulsory license is required to *satisfy court* that the patent owner has denied him/her a contractual license on reasonable terms and time, and gives guarantee "satisfactory to the court" to remedy the deficiency created by the patent owner. This is unrealistic because it envisages a situation where there is only one applicant and therefore the need for him/her to guarantee sufficient supply, which in most cases is not possible for a single producer. Other applicants should always be free to apply since a compulsory licence is non-exclusive. This requirement will thus only serve to scare away small, young producers who are likely to be the applicants in Uganda, yet their participation is needed to develop national technological and manufacturing capacity in the long term in addition to supplying the medicine.

b) Lengthy court procedures

The requirement to go through court places an undue burden on applicants to comply with court technicalities and wait for a long time to get hearings fixed. Courts are meant to deal with contentious matters; non-contentious matters are better handled under administrative procedures. Applying through National Drug Authority or the Ministry of Tourism, Trade and Industry would simplify the process so that all who can produce the patented medicine quickly enter the market to increase supplies or offer lower prices or both. By opting for a more rigorous procedure the drafters failed to make use of the freedom to determine the most appropriate method of implementing Trips agreement, a flexibility earlier mentioned.

c) Market restrictions

Article 63 (2) (b) provides that compulsory licensing shall be limited predominantly for the supply of a regional market. This suggests the condition in article 31 (f) of the TRIPS Agreement, which has been contested and waived. The only difference is that article 31(f) talks of the local market while the draft provision talks of regional market which may not make a difference depending on the geographical scope one has in mind.
In the current thinking within the context of the August 30th 2003 Decision, there is no need for such a provision in national law.

3. Parallel Importation

The draft bill provides that government can only import branded drugs put on the market by the patent holder or with his express consent. Drugs manufactured under government use order or by a compulsory licensee cannot be imported. This limits government's options in sourcing affordable medicines and to be changed. Although this provision seems to utilise the cherished "international exhaustion" regime, the requirement for "express consent" is undesirable as it restricts the parameters of interpreting the consent. The use of the word consent without qualification would be more appropriate while at the same time being within the allowed standards envisaged under Trips agreement.

4. Government Use Order

The TRIPS Agreement grants the government the right to use the patented invention without the authorisation of the patent owner. The draft bill makes a provision for *government use* but it subjects the government to consultation with the patent owner. This may give the patent owner the opportunity to make objections thus failing the policy goal of the government. Government has unfettered right issue the order and inform the patent owner afterwards. An obligation to *consult* is not a requirement under TRIPS and will make the law more restrictive than TRIPS requires.

Secondly, the draft bill restricts government use to situations where the patent owner is *anti-competitive*, yet the TRIPS Agreement allows the issuance of a government use order for *any reason* as long as the patent holder is compensated.

5. Utilising the Extension Period

The Doha Declaration allows the least developed countries not to grant or enforce patents on medicine until 2016 or any further period as the TRIPS Council may determine. While it is desirable that Uganda takes advantage of this extension, the draft bill has extended the grace period to 2016 without providing 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.

In addition, the exclusion of patents on medicine is placed in the section of articles which are not regarded as inventions. This may be interpreted to mean that medicines are not inventions, which is not the case. Medicines are inventions, which for the time being are excluded from patentability until 2016 or any further period as may be extended by the Trips Council.

It will suffice to make a stand-alone provision which recognises medicine as a patentable invention but which will not be operational until 2016 or any further period as the TRIPS Council may determine.

6. The Solution for Country with Insufficient or no Manufacturing Capacity

The TRIPS Council passed a decision on 30 August 2003 which allows the importation or export of products produced under compulsory license provided that the country of export and the country of import have issued such licenses and notified the TRIPS Council of such importation or exportation. It is worth Uganda implementing at least some aspects of this solution in the national in as simple a way as is legally possible. In particular, it should provide for export to other markets in the region and that importing countries do not have to pay remuneration (to the patent owner) as it will have already been by the exporting country (Uganda).

Conclusion

As a net consumer of technology, Uganda should not feel compelled to offer IP protection of similar strength with those countries which are exporters of technology. Moreover, its position as a member of the least developed countries allows it to have a patent law that is as flexible as possible in order to create conditions for the much desired development of its manufacturing capacity through research with and on the available technologies.

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