MAKING FULL USE OF TRIPS FLEXIBILITIES IN PATENT LAWS

A critical Review of Uganda's Draft Industrial Property Bill

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Introduction

Since the year 2000, Uganda Law Reform Commission has been spearheading the process of reforming Uganda's patent legislation. The reform is taking place in the context of the Doha Development Agenda, a process for continued negotiations on areas of concern within the WTO agreements raised by developing countries during the Fourth Ministerial Conference in Doha, Qatar in November 2001

The WTO agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and public health is one of the issues on the negotiation table. The main objective of these negotiations is to iron out the TRIPS implementation challenges faced by developing countries.

In addition there was increasing anxiety in the country regarding the impact of patents on access to medicine and how the new patent law will redress it. This anxiety was echoed by the concerns from civil society about the lack of consultation at the national level in the initial stages of the reform process. Uganda has finally come up with the draft Industrial Property Bill which is, at the time of writing this paper, awaiting consideration by Cabinet before it is presented to Parliament. In this paper, we analyse Uganda's draft Industrial Property Bill 2007 in the context of use of patents and public health with particular focus on access to essential medicines. The paper identifies the provisions of the WTO TRIPS Agreement commonly referred to as "TRIPS Flexibilities" and analyses the manner in which they have been incorporated in the draft IP bill in order to determine their impact on access to medicines. This work, which builds on an earlier analysis of the previous draft bills, seeks to place the draft bill in the context of new developments and thinking in the area of patents and public health while at the same time laying emphasis on the provisions pointed out in the memorandum to the Uganda Law Reform Commission that may not have been improved.

Background

In 1994, Uganda signed the WTO agreements, including the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The agreement sets minimum standards for the protection of intellectual property rights in all fields of inventions. The main feature of TRIPS in terms of public health is that it extended patent protection to pharmaceuticals, which were hitherto not patentable in many countries. The major obligation created by the TRIPS Agreement was that all members of the WTO must revise their laws to conform to the standards set in the agreement.

Safeguards/Flexibilities in the TRIPS Agreement

During the drafting of the TRIPS Agreement, a number of provisions, commonly referred to as "flexibilities", were built in the agreement to enable member countries, especially the developing and least developed ones, to design national patent laws that allow them to increase access to affordable medicine by their citizens. This came out of the realisation that potentially, patents have adverse impacts on access to medicine. The term

flexibilities was and continues to be used to express the freedom governments have to tailor these provisions to suit their circumstances.

The following are the flexibilities/safeguards in TRIPS Agreement:

- Member countries are not obliged to implement in their national law, more extensive protection than is required under TRIPS Agreement.[1]

- Members are free to determine the appropriate method of implementing the provisions of TRIPS Agreement within their own legal systems and practice.[2] This calls for great care on the side of national governments when drafting national patent regimes to avoid procedures that slow or make it difficult to achieve certain social objectives.

- Members are exempted from any legal action relating to parallel importation provisions.[3] This means that members are free to adopt any parallel importation regime without fear of any threat, action or reprisal from any member or organisation.

- The objectives of the agreement set out in article 7, which state that the protection and enforcement of intellectual property rights should contribute:
    a) To the promotion of technological innovation
    b) To the transfer and dissemination of technology
    c) To the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare,
    d) To a balance of rights and obligations, and

- The freedom in formulating or amending national legislation and regulations:
    a) To adopt measures necessary to protect public health and nutrition
    b) To promote the public interest in sectors of vital importance to their social-economic and technological development.[4]

Under this provision, members are free to adopt measures to prevent abuse of intellectual property by owners or the resort to practices that restrain trade or adversely affect the international transfer of technology. Such measures should however be consistent with TRIPS agreement.

- The other flexibility offered by the TRIPS agreement is **the freedom granted to members to provide limited exceptions to the exclusive rights conferred by patents**. Such exceptions however should not unreasonably conflict with the

[1] Article 1
[2] Ibid
[3] Article 6
[4] Article 8

normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner, taking into account the interests of third parties.[5]

- The most controversial flexibility is article 31. This provision allows "**other use of the patented invention without the authorisation of the patent owner**". This can arise in two situations:
    a) Where government uses the invention itself or through an agent
    b) Where government grants a compulsory licence to other manufacturers to work the invention. In the case of pharmaceuticals, other use includes the production of a generic version of the patented medicine)[6]

Transitional Arrangements

Compared to the developed countries, least developed countries (LDCs) have special needs and requirements: they still face economic, financial and administrative constraints; and they need flexibility to create a viable economic base and to benefit from a strong intellectual property system (*emphasis added*). This was observed during TRIPS negotiations. Consequently compliance with trips was segmented. Developed countries were required to comply on entry into force of the agreement. Developing countries were given 5 years after entry into force while least developed countries were given 10 years. This means that LDCs were given up to January 2006 to implement the TRIPS Agreement. During the Doha Ministerial Conference, it was observed that LDCs still faced economic, financial and administrative constraints. The Doha Declaration therefore extended the transitional period to 2016 in the case of medicine. This means that Uganda is not obliged to grant patents on medicine till 2016.

Implementation Problems

With these flexibilities or safeguards in the TRIPS Agreement, one may be tempted to ask why the developing countries are not utilising them for their advantage. The controversies that emerged in the aftermath of TRIPS implementation after its entry into force and which were raised in the first Ministerial Conference in 1996 provides an answer. Developing countries, which attempted to implement these safeguards in the initial stages, received threats of sanctions and, in extreme cases, legal action. In other cases, developed countries have used bilateral pressure to scare developing countries away from appropriate use of these safeguards. The known examples are Thailand, South Africa and Brazil. Probably other cases went and still go unnoticed.

Developing countries began to raise the issue of implementation challenges at the first Ministerial Conference albeit amidst opposition from the developed member countries. The excesses of this are what led to the failure of the Seattle Ministerial Conference in

[5] Article 30

[6] This grant of compulsory licence means that it was made against the will of the patent owner. Ordinarily, where a third party desires to manufacture a product whose patent term is still running, he applies to the patent owner who may grant a voluntary license. A compulsory license therefore is granted by government where it has proved impossible to get a voluntary one at reasonable terms.

1999. The Doha Declaration adopted by the Ministerial Conference in November 2001 was a step to clarify the right of developing countries to make use of the TRIPS flexibilities in built safeguards. However, while most of the implementation problems were addressed by the Declaration, the question of how countries with limited or no manufacturing capacity may make use of compulsory licensing provisions remained unresolved. The TRIPS Council was mandated to work out a decision by December 2002. The negotiations became protracted and a solution was reached on August 30th 2003. The decision put in place a procedure for importation and exportation of medicine produced under compulsory licence or government use order.

Therefore, national efforts to revise patent legislation must necessarily take into account the Doha Declaration and the outcome of the negotiations on paragraph 6.

Compliance Vs National Strategic Objectives

While compliance with the TRIPS Agreement is an obligation, the major consideration in reforming the law should be Uganda's strategic interests. In terms of public health, the patent regime will serve Uganda's interests if it enables the country to increase the availability and affordability of medicines in the country. This may be achieved through a number of ways:

- Developing the capacity at national level for generic production.
- Allowing the widest possible scope for parallel importation
- Adopting a simple and expeditious procedure for compulsory licensing
- Extensive flexibility for early working
- Disallowing data exclusivity

TRIPS Flexibilities Relevant to Access to Medicine

As indicated above, this work builds on the work done on the previous draft Industrial Property Bill. In a memorandum presented to the Uganda Law Reform Commission in June 2002, proposals for revision were made on the following provisions.

- Patentability: This related to the patenting of new uses for patented products.
- Early Working or Bolar Exception
- Government Use Order
- Compulsory Licence
- Parallel Importing
- Extension of the Transitional period

The above provisions have direct implications for access to medicine especially by the poor in any country among the least developed countries. Therefore it matters how well they are incorporated in the national patent law if the country is to derive maximum health benefit from the patent system. Uganda's draft Industrial Property Bill attempted to incorporate these TRIPS Flexibilities. However, some of them were drafted in a restrictive style such that Uganda may not derive maximum flexibility as envisaged by TRIPS Agreement, the Doha Declaration and other non-legally binding instruments. The

need to identify national strategic objectives before enacting the law should underpin the patent law revision process.

The significance and implications for access to medicine of these provisions may be well appreciated The drafting of the following provision need revision.

Early Working Exception

Sometimes referred to as "bolar provision", early working exception one of the exceptions allowed under the flexibility provided by article 30 of TRIPS Agreement. The exception allows the government to increase availability and affordability of drugs through early entry of generic versions into the market. The provision enables any interested person or entity to use a patented invention for research and to do testing, secure approvals, and registration of the product of such research so that the product enters the market as soon as the patent expires. In the absence of such a provision, one has to wait until the expiry of the patent term to begin testing, applying for regulatory approvals and registration. This indirectly extends the patent term of the drug in question considering that it may take a number of years to accomplish such a process.

The draft Industrial Property Bill provides for bolar exception in a restrictive sense. Uganda's interest is to use this exception in its fullest extent.

> ***S.45 (1): The rights under the patent extend only to acts done for industrial or commercial purposes but do not extend to acts done for scientific research.***

This provision is very narrow and restrictive. It limits the rights under the patent only in the case of scientific research but not in case of acts done for industrial or commercial purposes. Acts such as testing, seeking regulatory approval and registration are done for industrial and commercial purposes. Carrying out those activities means that entry of generic products will occur as soon as the patent expires. But if on the other hand such procedures are done at the expiry of the patent, one would have to wait for years to have generic products on the market. This delayed entry of cheaper products also means that the patent enjoys more years of monopoly while access to cheaper generic medicine remains illusive for the majority poor people.

This provision exists in the current patent statute, which predates TRIPS Agreement, in almost similar wording. It is important to note that the negotiations of the TRIPS Agreement created a shift in the thinking regarding this matter. The new thinking has been taking shape to what is currently understood as the right of any generic manufacturer to not only engage in scientific research using the patented invention but also to go a head and obtain regulatory approvals including registration of the generic version in readiness for sale upon expiry of the patent on the drug in question. That is why the right of members to provide for limited exceptions was left flexible and that is the only way a member state can make full use of that flexibility. The draft Industrial Property Bill therefore fails to capture this new thinking.

The Recommended Provision:

> ***The exclusive rights of the patent owner shall not extend to acts done for scientific research or for the purpose of testing, obtaining regulatory approvals and/or registration for the purpose of commercializing the product after the expiration of the term of the patent.***

Other use without the authorisation of the patent owner, Article 31

In addition to Article 30 of TRIPS Agreement, Article 31 provides other circumstances where the patented invention may be used without the authorisation of the patent owner.

(A) Compulsory Licensing

Compulsory licensing refers to the grant of a licence by government to an applicant for the production of a patented product without the consent of the patent owner. This is one of the most controversial flexibilities in the TRIPS Agreement.[7] This controversy not withstanding, governments have the freedom to incorporate it in national legislation. A compulsory licensing provision is a tool for reducing prices and increasing availability of drugs to the population. Many developed countries have historically used compulsory licensing and continue to do so without challenge. A notable example is the attempt by USA and Canada to issue compulsory license for *Ciplofloxacine* when they were under threat of anthrax attack following the September 11 terrorist attack. Following this precedent, developing countries now have all the legitimacy to have such a provision in their laws.

The draft Industrial Property Bill contains provisions on compulsory licensing under section 60. But this provision is still modelled on the provisions of the TRIPS Agreement and also fails to capture the new thinking regarding compulsory licensing.

> **60 (1) provides that "at any time after <u>four years from</u> the filing date of an application or three years from the grant of a patent, whichever period last expires, any person may apply to the court for a licence to exploit the patented invention on the grounds that a market for the patented invention is <u>not being supplied</u> on reasonable terms in Uganda".**

The pre-conditions for grant of a compulsory license under S.62 create barriers. It provides that;

"A compulsory license shall not be granted unless the person requesting the license

> **(a) satisfies court that he or she has asked the owner of the patent for a contractual license but has been unable to obtain**

[7] Article 31

the license on reasonable commercial terms and within reasonable time
(b) offers guarantee satisfactory to the court to work the relevant invention sufficiently to remedy the deficiency or to satisfy the requirements which gave rise to his or her request

Compulsory licensing makes greater sense if the process of granting it is simple and expeditious. It is in the interest of Uganda to have this process simplified so that all who can produce particular products enter the market to either increase supplies or offer lower prices as quickly as possible. The precondition in this draft provision envisages a situation where there is only one applicant and therefore the need for him or her to guarantee sufficient supply. The import here is that if there are a number of applicants and none can offer such guarantee individually, none will get a compulsory licence. In the majority cases, it is not possible for a single compulsory licensee to guarantee to work a particular invention to remedy the deficiency or to satisfy the requirements that gave rise to the application. This would scare away the young industries and have a long term impact on the development of technological and manufacturing capacity. In addition it places undue burden of proof on an applicant. The burden should be placed on any person alleging lack of such capacity. The precondition therefore defeats the purpose of compulsory licensing.

There should be a presumption of capacity on the part of the applicant for a compulsory licence to produce sufficient quantities. If the deficiency persists, other applicants can apply since a compulsory licence is non-exclusive. Emphasis should be put on the quality of products which falls in the province of other administrative authorities such as National Drug Authority which approves drugs to be put on the market in Uganda

The other problem with this kind of provision is the role of court. Court operates better in contentious matters. Non-contentious matters are better handled under administrative procedures. The procedure of obtaining remedy from court is usually technical and requires particular formats of applications. Courts are usually handling all sorts of cases and tend to take a little longer to fix hearings. These technical and procedural niceties may delay the process hence elongating the period within which the desired goal is achieved. It is therefore simpler and more expeditious to have compulsory licensing proceedings take place in administrative authorities instead of courts of law.

The provision should be revised to read as follows:

(a) satisfies the relevant authority **that he or she has asked the owner of the patent for a contractual license but has been unable to obtain the license on reasonable commercial terms and within reasonable time**
(b) satisfies the relevant authority **that he has the capacity to work the invention and to supply the market in reasonable quantities.**

Parallel Importation

Section 45 (2) of the bill provides that**:**

> ***"The rights under the patent shall 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 express consent".***

Under this provision, government can only import branded drugs put on the market by the patent holder or by the persons licensed by him. Drugs manufactured under government use order or by a compulsory licensee cannot be imported because they are not manufactured with the consent of the patent holder. This limits the choice of government seeking to source for the lowest drug price.

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 Decision, there is no need for such a provision in national law.

The Current Law

The rights of an owner of a patent ….shall not extend to acts in respect of articles which have been put on the market in Uganda by an owner of the patent or with his express consent.

The departure made in the draft provision is that while the current law favours national exhaustion of rights, the draft provision prefers international exhaustion of rights. However, both provisions require express consent of the patent owner and are equally restrictive.

There has been a shift in thinking regarding parallel importation. Since products may be on the market through other legitimate means such as compulsory licence or government use order, and since members have all the freedom to determine their parallel importation scope without any risk of legal action, it is prudent for national law to provide for the widest scope of parallel importation.

Proposed provision

The rights under the patent shall not extend to acts in respect of articles, which have been legitimately put on the marketing Uganda or anywhere in the world.

This proposed provision enables government to import drugs that have been produced under a compulsory license or government use provisions both of which are legitimate channels of production under TRIPS. The provision presents no problem since it cannot be a basis of litigation under the WTO dispute Settlement system.

Government Use Order

The government use provision grants the government the right to use the patented invention without the authorisation of the patent owner. This kind of provision is also allowable under article 31 (other use without the authorisation of the patent owner). Ordinarily, once the government has invoked this right, it need not consult the patent owner. It suffices to inform such owner.

The draft bill makes a provision for government use under section 68 as follows. Our interest for purposes of this analysis is sect. 68 (b)

Where:

> *b) the Registrar determines that the manner of exploitation of an invention by the owner of the patent or his or her licensee is not competitive, the Minister may, upon application to him or her in the prescribed form and after consultation with the Industrial Property Department and the owner of the patent, order that the protected invention shall be exploited by Government Ministry, Department, agency or other person as the Minister may designate in the order subject to the payment of adequate compensation to the owner of the patent in accordance with this section.*

The main concern with this provision is that 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. Such an obligation is not a requirement under TRIPS. Enacting it makes the patent law TRIPS Plus meaning that it is more restrictive than TRIPS requires.

Proposed wording:

Where:

> *c) the competent authority determines that the manner of exploitation of an invention by the owner of the patent or his or her licensee is not competitive, the Minister may, upon application to him or her in the prescribed form and after consultation with the Industrial Property Department, order that the protected invention shall be exploited by Government Ministry, Department, agency or other person as the Minister may designate in the order*

> *Provided that the patent owner shall be informed of such decision and paid adequate compensation in accordance with this section*

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. The 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. It may b the transitional period indicated above.

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.

The Solution for Country with Insufficient or no Manufacturing Capacity

This is the subject under the Paragraph six of the Doha Declaration. Paragraph 6 acknowledged that countries with insufficient or no manufacturing capacity may find it difficult to make use of compulsory license. The TRIPS Council was instructed to find a solution by end of 2002. 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. The implementation of the decision and the procedures it lays down is yet to be tested for its workability and usefulness. Since the adoption of the 30 August decision, only Rwanda has issued such a notification to the TRIPS Council.

Conclusion

Although the draft bill has been improved in a number of aspects, there is still need for improvement on the drafting language to make use of the flexibilities in the widest allowable sense and capture the new thinking regarding these flexibilities. Uganda is a net consumer of technology. It should not feel compelled to offer intellectual property 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 development of its manufacturing capacity through use of available technologies through research and production.