REPUBLIC OF SOUTH AFRICA

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities

Topic 5: Overview of the Use of Patent-Related Flexibilities and the Main Constraints thereon within the Region

Durban, South Africa
January 29 to 31, 2013

OVER VIEW OF THE USE OF PATENT-RELATED FLEXIBILITIES AND THE MAIN CONSTRAINTS THEREON WITHIN THE (WEST AFRICAN) REGION

SHAFIU ADAMU YAURI,LL.M
PRIN ASST REGISTRAR,
TRADEMARKS,PATENT&DESIGNS
ABUJA NIGERIA

+2348033204663
sayauri@yahoo.com

- **What is TRIPs?**
- **World Trade Organization (WTO) Agreement on Trade Related aspects of Intellectual Property Rights ("TRIPs Agreement")**
- **Requires that all WTO members adopt certain minimum standards regarding intellectual property rights (IPR) by providing both guidance and binding policy directives**

TRIPs..

- **Covers a wide range of IPRs :**
  - **Copyrights**
  - **Trademarks**
  - **Geographical Indications**
  - **Industrial Designs**
  - **Layout Designs of Integrated Circuits**
  - **Trade Secrets**
  - **PATENTS**

OBJECTIVES..

- **Objectives of TRIPs Agreement**
- ***Article 7***
- **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**

MINIMUM REQUIREMENTS FOR WTO MEMBER STATES

- **Article 1.1 of the TRIPs Agreement states that members may, but are not required to go beyond the minimum standards!**
- **MINIMUM REQUIREMENTS-**
  - **Protection of Intellectual Property Rights in the 7 key areas mentioned earlier.**
  - **Term of Protection of 20 years**
  - **Protection against Anti-Competitive Practices**
  - **Protection of Undisclosed Information**
  - **Enforcement of Intellectual Property Rights**

PROTECTION OF IPRs

- ***Article 27.1***
  - **Patents shall be available for any invention, whether products or processes, in all fields of technology**
  - **Patents shall be granted for protection of inventions that are “new, involve an inventive step and are capable of industrial application”.**

Term of Protection

- ***Article 33***
- **The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date**
- **The length of this period is of critical importance. The longer the period, the longer the monopoly on the protected product or process.**
-
- **RATIONALE- IP protection encourages inventors and creators to earn benefits from their creativity. This encourages new inventions, such as new drugs, whose development costs can sometimes be extremely high, so private rights also bring social benefits.**
-

TRIPs FLEXIBILITIES

- **The TRIPs Agreement provides flexibility for governments to fine tune IP protection in order to meet social goals.**
- **It allows governments to make exceptions to patent holders' rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled.**

Flexibilities in TRIPs…

- Basic criteria for patentability are not defined in the Agreement, so members are free to determine under their domestic law how the following criteria are met:
  - What constitute Novelty
  - What constitute Inventive step
  - What constitute Industrial applicability
- Countries can set patentability criteria at the national level according to policy priorities e.g.
  - Healthcare priorities
  - Industrial development
  - Encouragement of innovation
  - Protection of natural resources

- NOTE-
- High standards for basic criteria of patentability will result in fewer patents. Adoption of minimum standards may facilitate entry of generics into the market.

List of Flexibilities

- Transition time (now available only to LDCs)
- Freedom to determine Patentability Criteria
- General Use and Research Exception
- Bolar Provision
- Parallel Imports, Grey Imports and 'Exhaustion of Rights'
- Compulsory Licensing
- Compulsory Licences for Exports (August 30th Decision)
- Flexibilities provided by the "Doha Declaration"
  - Drug price control and price negotiations
  - Full use of transition periods
  - Using judicial and competition authorities
  - Etc.

Patentability Criteria-***Article 27***

- ***, Governments can refuse to grant patents for three reasons:***
  - ***inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health — Article 27.2***
  - ***diagnostic, therapeutic and surgical methods for treating humans or animals — Article 27.3a***
  - ***Certain plant and animal inventions — Article 27.3b.***
-
- **Thus, methods of treatment, including for prevention, diagnosis or therapeutic, should be deemed non patentable**

Issues regarding Patentability Criteria…

- **The TRIPs Agreement does not explicitly exclude from patentability secondary or further uses of known substances. The patentability criteria for new uses must be clearly defined in national legislations. Otherwise two potential problems may arise:**
- **i-The potential for *evergreening* by introducing trivial, non-efficacious variants of existing chemical substances.**
- **ii- Redundant extensions and creations of 'next generation drugs' which result in superfluous variation to a product and then patenting it as a new application.**

. General Use and Research Exception

- *Article 30:Exceptions to Rights Conferred*
- **Governments can make limited exceptions to patent rights, provided certain conditions are met:**
- **The exceptions have to be limited**
- **They may not unreasonably conflict with the normal exploitation of the patent**
- **They should not unreasonably prejudice the legitimate interests of the patent owner**
-
- **EXAMPLES**
- **Teachers should be free to teach their students**
- **Freedom for medical practitioners to carry out medical treatments.**
- **Pharmacists should be free to make supply medicines to patients on the basis of individual medical prescriptions supplied to them by doctors without fear of patent infringement**
- **NOTE- The Patent Law of the People's Republic of China states in section 62 that using a patent solely for the purposes of scientific research and experimentation is not considered to be an infringement of the patent right.**

Bolar Provision

- **This provision permits the use of a patented invention without authorisation from the patent owner in order to obtain marketing approval of a generic product before the patent expires.**
- **NOTE-Generic manufacturers need to submit bioequivalence data for obtaining marketing approval, this can take years.**
-
- **NOTE THE CASE OF- *Roche Products v. Bolar Pharmaceutical*, 733 F.2d 858 (Fed. Cir. 1984), was a court case in the US related to the manufacturing of generic pharmaceuticals. Bolar was a generic drug manufacturer and Roche brand-name pharmaceutical company which made and sold Valium, the active ingredient (diazepam) which was protected by patent.**
- **Before patent expiration, Bolar used the patented chemical in experiments to determine if its generic product was bioequivalent to Valium in order to obtain FDA approval for its generic version of Valium. Bolar argued that its use of the patented product was not infringement under the experimental use exception to the patent law. Bolar also argued th at public policy in favor of availability of generic drugs immediately following patent expiration justified the experimental use of the patented chemical because denying such use would extend Roche's monopoly beyond the date of patent expiration.**
- **The court rejected this argument, stating that such policy decisions should be made by Congress. Shortly after Roche v Bolar was decided, Congress did pass a law permitting use of patented products in experiments for the purpose of obtaining FDA approval (section 271-e-1 of the Drug Price Competition and Patent Term Restoration Act, informally known as the "Hatch-Waxman Act" [Public Law 98-417], which established the modern system for FDA approval of generic drugs.**
-

EC-Canada WTO Dispute on Bolar Exception...

- **<u>EC-Canada WTO Dispute on Bolar Exception</u>**
- **In 1993 Canada amended its patent Act to include Bolar type exemption**
- **- Canada's bolar provision allowed the manufacture the day after patent expiry**
- **- Also allowed for stockpiling of generic product in the six months before patent expiry**
- **- EC took issue with both provisions, invoked WTO Dispute Settlement Mechanism in1998**
- **WTO dispute Settlement panel found that early working exception is consistent with Article 30 of TRIPS (see WT/DS114/R)**
-
- **NOTE - The Bolar Provision allows a generic product to enter the market more quickly after patent expiry, which in turn facilitates access to cheaper medicines.**
-

Disclosure Requirements

- ***Article 29 :Conditions on Patent Applicants***
- **Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application. Lack of sufficient disclosure may be a reason for refusal of an application or invalidation of a patent.**
- **Important element in the assessment of patent applications especially for developing countries with limited capacity for examination of patents.**
- **Of major importance in pharmaceuticals to enable the reproduction of the invention during the patent term (for instance, in the case of a compulsory licence) or after patent's expiry.**
- **NOTE- IP Protection can also serve social goals. Disclosure of a patented inventions allow others to study the invention even while its patent is being protected thus promoting technological progress, technology dissemination and transfer. The invention becomes available for others to use after the protection expires. This prevents "re-inventing the wheel".**

. Parallel Imports, "Grey Imports and Exhaustion of Rights"

- *Article 6:Exhaustion of Rights*
- **National patent laws can provide that once a patent owner sells its goods in any country it has no right to control the resale of those goods (regime of international exhaustion).**
  - **It is the import and resale in a country of a patented product that has been legitimately put on the market of the exporting country.**
  - **No need for consent of patent holder**
  - **Doha Declaration on TRIPS and Public Health affirms the right to choose Exhaustion of rights: national, regional or international regimes.**
  - **In Nigeria,S.6(3) of the Patent and Designs Act 1970 provides;**
- **The rights under a patent-(a)shall extend only to acts done for industrial or commercial purposes, and (b) shall not extend to acts done in respect of a product covered by the patent after the product has been lawfully sold in Nigeria..."**
-

Compulsory Licensing

- *Article 31:Other Use Without Authorization of the Right Holder*
- **Government has the right to grant licences to 3rd party or governmental institutions to use a patent without consent of the Patent holder for reason of public policy or to promote public interest. Patent holders are to receive adequate compensation, usually in a form of royalty.**
- **Compulsory licenses are issued in the public interest to address environmental, public health, national security or economic development concerns by promoting third-party production of the patented products at lower prices and/or greater quantities than are otherwise available.**
- **NOT just for emergencies and NOT limited to certain diseases (as reaffirmed in Doha Declaration on Public Health).**

. The Doha Declaration

- *"We affirm that the (TRIPS) 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 Ministerial Declaration on the TRIPS Agreement and Public Health of November 14, 2001

Flexibilities Affirmed by the Doha Declaration

- **The right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted**
- **The right to determine what constitutes a national emergency or other circumstance of extreme urgency.**

WAIVERS FOR LEAST DEVELOPED COUNTRIES (LDCs) AND OPPORTUNITIES FOR REGIONS WITH MORE THAN 50% LDCs

- **Article 66 and Para 7 of Doha (exemptions for LDC)**
- **Least Developed Countries (LDCs) have been exempted until 2016 from the obligation to implement patent protection in the health sector.**
- **This allows the compulsory issue of licenses for the import, export and production of essential medicines.**
- **These transition periods are subject to further extensions upon duly motivated request - Article 66.1**

On LDC's...

- **For pharmaceuticals and undisclosed information, option has been further extended to LDC's in Paragraph 7 Doha Declaration**
- **"We also agree that the least developed country Members WILL NOT BE OBLIGED, with respect to PHARMACEUTICAL PRODUCTS, TO IMPLEMENT OR APPLY Sections 5 (on Patents) and 7 (on Protection of Undisclosed Information) of Part II of the TRIPS agreement OR TO ENFORCE RIGHTS provided for under these Sections <u>UNTIL 1 JANUARY 2016</u> WITHOUT PREJUDICE TO SEEK OTHER EXTENSIONS of the transition periods as provided for in Article 66.1 of the TRIPS Agreement."**

See Cambodia's Patent Law

- **<u>National Experience: Cambodia</u>**
- **Art 136: Cambodian Patent Law:**
- **"The pharmaceutical products mentioned in the Article 4 of this Law shall be excluded from patent protection until 1 January 2016 according to the Declaration on TRIPS and Public Health of the Ministerial Conference of the WTO dated November 14, 2001 in Doha of Qatar"**

- **NOTE Article 66: LDCs**
- **Article 66.1:**
- **“The Council for TRIPS SHALL, upon duly motivated request by a least developed country Member, accord extensions of this period”**
- **For all the provisions of the TRIPS Agreement, Patents, Copyright, Trademarks etc ….LDCs have the option to make a request for further extensions beyond 2016**
- **Country Experience: Maldives applied for extension to TRIPS Council and has obtained the extension.**
- **West Africa?**
- **Other African countries??**

Regional Trade Areas with >50% LDCs

- **Regional Trade Areas constituting more than 50% LDCs that share the same health problem can take advantage of the overall LDC status of the region.**
- **It is important to note that the ECOWAS region is constituted of 73% LDC countries. The entire region can therefore be considered as LDC and stands to benefit from using the flexibilities and timelines available to LDCs.**

Conclusion

- **Implementation of the TRIPs Agreement is an international obligation, which places responsibility on member countries to incorporate in their national laws. However, implementing this obligation requires a well-informed effort not to include additional burdens beyond the minimum level of protection required.**
- **Member States in the African Region need to follow the example of other developing/LDC countries that have made great advances in the use of TRIPs flexibilities to address national and regional needs.**

- **POTENTIAL CHALLENGES TO TRIPS IMPLEMENTATION**
- All the efforts to implement TRIPs flexibilities in national legislation could be nullified if Member States allow any of the under listed provisions, sometimes included in FTA's, to trickle into bilateral agreements and possible inclusion in national legislations**.**
- Limiting the grounds and conditions under which compulsory licenses may be issued;
- Providing for the possibility of extensions of patent terms beyond the 20 years required by TRIPs;
- Requiring Drug Regulatory Authorities, most of which have limited expertise in IP matters, to consider the patent status of medicines before granting marketing authorization to generic manufacturers (known as "linkage");
- Requiring test data exclusivity which prohibits reference to already existent clinical test data on pharmaceutical products by generic applicants to obtain registrations of bioequivalent products. Data exclusivity restricts drug regulatory authorities from accepting such applications and/or approving generic medicines for a certain period of time. These restrictions could delay the entry of generics into the market for several years.
- Requiring the countries to expand the national criteria for patentability, which in turn increases the number of patents granted for incremental improvements, thus increasing monopolies;
- Extending intellectual property enforcement measures beyond the requirements of the TRIPs Agreement, thereby actively hindering generic production, or discouraging such products from entering national markets.

THE WAY FORWARD

- The need for countries in the Region to review and incorporate in national legislation TRIPs flexibilities is long overdue. The region is losing opportunities for improving her peoples' health and development by not taking full advantage of the TRIPs Flexibilities.
- Africa needs to follow the example of other developing /LDC countries that have made great advances in the use of TRIPs flexibilities to address national health emergencies and improved access to cheaper generic medicines.
- Implementation of TRIPs Agreements is an international obligation, which places responsibility on member countries to incorporate in their national laws. However, implementing this obligation requires a well-informed effort not to include additional burdens beyond the minimum level of protection required.

GRAPIC PRESENTATION OF THE CURRENT SITUATION IN ECOWAS REGION

See annexures: