Intellectual Property Rights Protection in Least Developed Countries: Options Availaible

Seminar on:
Who Will Live and Who Will Die
10-12, April, Dhaka, Bangladesh

HAI -AP

TRIPS and LDCs

- Article 1 of TRIPS: Members are **not obliged** to provide **more protection** than is required by TRIPS.
- Members have freedom to determine appropriate method of implementing the provisions of TRIPS within their **own legal system** and practice
- **LDCs have lesser obligations** in some areas: longer **transitional periods** before implementing obligations
- Status of LDCs is particularly important in the case of **pharmaceuticals** because of the **Doha Declaration** and decisions relating to it.

Transitional Period for LDCs – TRIPS

Comply with TRIPS obligations (art. 66.1) :

- **Developed country -- after one year.**
- **Developing countries – after five years (2000)**
- **LDCs -- after ten years (2006)**

Article 66.1 also provides : "The Council for TRIPS shall, upon duly motivated request by a least developed country, accord extensions of this period."

Transitional Period is for ALL sectors

Transitional Period for LDCs – Doha Declaration

- **In case of Medicines, the WTO now allows an additional period of transition for LDCs.**
- **Doha Declaration (para 7):** ***"We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement."***
- **Paragraph 7 was affirmed by the TRIPS Council in a decision of 27 June 2002.**

Transitional Period for LDCs – Doha Declaration (contd..)

- Thus, for **medicines, LDCs do not have to implement** and apply the TRIPS provisions on **patents** (Section 5) and on **undisclosed information** (Section 7) until **1 January 2016.**
- For LDCs that have **already allowed for patents** relating to pharmaceutical products, **can amend their laws to now exclude** pharmaceutical products from the grant of patent protection, until at least 2016.

Mailbox Obligation

- **Art. 70.8 (a) of TRIPS:** ***where a WTO member does not make available (as of the date of entry into force of the WTO agreement) patent protection for pharmaceutical and agricultural chemical products, that Member shall provide (as from the date of entry into force of the WTO agreement) a means by which applications for patents for such inventions can be filed.***
- **This provision is often referred to as the "mailbox" obligation.**

Exclusive Marketing Right

- Article 70.9 of TRIPS: where a product is the subject of a patent application in a Member in accordance with Article 70.8 (a), **exclusive marketing rights shall be granted** for a certain period provided that (after the entry into force of the WTO agreement) a patent application has been filed and a **patent granted for that product in another Member** and **marketing approval obtained in that other Member.**
- For these provisions, **no exemption for LDCs in TRIPS or Doha Declaration**

Waiver on EMR

However, on 8 July 2002 the WTO General Council approved a draft waiver on EMR submitted by the TRIPS council.

"1. The obligations of least developed country Members under paragraph 9 of Article 70 of the TRIPS Agreement shall be waived with respect to pharmaceutical products until 1 January 2016

2. This waiver shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement".

Waiver on Mailbox Applications?

- There is **no waiver or clarification** about the "mailbox obligation" (contained in Article 70.8 (a) in respect of LDCs.
- However, **Article 70.8 suggests that the mailbox obligation would not apply to LDCs that made available patent protection** for pharmaceutical and agricultural chemical products as of 1 January 1995 (the date of entry into force of TRIPS). This suggests that the **obligation also does not apply to these LDCs if they later removed the protection** to take advantage of the extension of the transitional period until 2016.

Pharmaceutical Process Patents and LDCs

- Para 7 of Doha Declaration, does not explicitly exempt Process Patents from being granted by LDCs until 2016.
- However, opinion that para 7 although referring to only "pharmaceutical products" also includes process patents.
- Argued that since the Article 28.1 (b) of the TRIPS Agreement grants protection to products directly obtained from a patented process, the extension of the transitional period should also be deemed to apply to process patents.
- The EC "*all least developed Members benefits from the extension of the transition period from 1.1.2006 to 1.1.2016 (and probably beyond) with regard to product and process patent protection and its enforcement*"

Protection of Undisclosed Information (Data Protection/ Exclusivity)

- **Section 7 of TRIPS : Protection of undisclosed information against unfair competition.**
- **Article 39.3 requires Members to protect test data of the patent holders against "unfair commercial use."**
- **Para 7 of the Doha Declaration specifically exempts LDCs from implementing the obligations in this section (Part II, Section 7) until 2016.**

Incorporating Waiver Till 2016 in National Law

- TRIPS as well as the Doha Declaration and subsequent decisions relating to it contain **flexibilities for LDCs to choose between various policy options**.
- However, whether and to what extent a LDC makes use of the existing flexibilities are matters that are **determined by national policies and laws**.
- **Many LDCs already have national laws granting patents for pharmaceuticals (30 of 32 in Africa)**
- LDCs are **allowed to reverse legislation**, policy or practice that currently grants patent protection for pharmaceutical products.

Example:

Cambodia patent law of 2003, under the heading of "Transitional Provision" provides that:

"The pharmaceutical products mentioned in the Article 4 of this Law shall be excluded from patent protection until January 01, 2016, according to the Declaration on Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health of the Ministerial Conference of World Trade Organization dated November 14, 2001 in Doha of Qatar."

Consequences of "Reversing" Patent Protection

- Possible, there may be issues as to the rights of a patent holder, should existing patents be suspended or cancelled -- may need to provide for appropriate compensation.
- In any case, all future potential patents on drugs need not be granted

Options for LDCs

- **Continuing to grant patent protection to pharmaceutical products;**
- **Revising the present patent law so as to exclude drug patents, and compensation is not paid;**
- **Revising the law so as to exclude drug patents, and compensation payment is offered to patent holders to cancel or suspend their patents;**
- **Allowing present patents to continue operating, but disallowing the grant of patents for pharmaceutical products in future (until 2016 and beyond).**

Options for LDCs (contd..)

- Decide **not to enforce the rights** given to the patent holder --Para 7 of the Doha Declaration allows LDCs to not enforce rights granted to patent holders. Thus **enforcement authorities in the LDCs can refuse to enforce the rights** given to the patent holder.
- May require some kind of **payment of compensation** to the patent holder

Opportunities for Bangladesh

- Uniquely Placed as an LDC with a developed Pharmaceutical Industry
- More than 150 functional pharmaceutical companies
- Some APIs already being produced
- Already exporting to more than 60 countries
- Change in Indian Patent Act allows increased opportunity
- Can become a hub for generic drug manufacture
- Can use Para 6 of Doha Declaration and the July 30, 2003, Decision of TRIPS Council to export
- If Bangladesh amends National Law, it need not make use of a Compulsory License to export under this decision

New Issues in IP Protection

Data Protection/ Exclusivity

- Data exclusivity is a practice whereby, for a fixed period of time (usually 5 years), drug regulatory authorities do not allow the data that the originator company files to get marketing approval, to be used to register a generic version of the same medicine.
- Means that if an MNC gets marketing approval for a drug based on data of clinical trials, the same data cannot be used to register a drug by another (generic) company.
- The latter, in spite of the fact that it is wishing to register the same drug, will be forced to conduct fresh clinical trials before its version of the drug can be registered.

Difference in Patent and Drug Regulatory Enforcement

- **Medicines subject to two sets of rules: Intellectual Property Rights (include Patent protection) and registration of drugs before marketing approval.**
- **Former regulated by a country's Patent laws while the latter is regulated by the drug regulation authorities**
- **Patents are a private right -- a right that the Patentee enjoys and the onus is on the Patentee to ensure that it is not infringed**
- **Drug regulatory authority is a body set up as a public authority -- function is to ensure, in public interest, that drugs that are provided with marketing approval meet the criteria of safety, efficacy and good quality.**

- Under Data Exclusivity, being sought that drug regulatory authorities should act on behalf of pharmaceutical companies to safeguard their monopoly right.
- Being asked to reject the application for marketing of a drug by a local company if it doesn't submit fresh data from its own clinical trials.
- Cannot be within the domain of regulatory agencies.
- If agency has approved a drug based on clinical data provided by one company, there is no logical reason why the same drug should be refused marketing approval if another company produces it.
- For the issues of safety and efficacy have already been taken care of when the originator company's drug was given approval.

TRIPS Does NOT Mention Data *Exclusivity*

TRIPS agreement (Article 39(3)): “ ***Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use”.***

TRIPS does not mention “data exclusivity”
but “data protection”

TRIPS Does NOT Require Data Exclusivity

Carlos Correa, noted Patents expert:

"The Agreement does not oblige to recognize any kind of exclusivity on data submitted for approval, since the protection should be granted under the discipline of "unfair competition"….

Once data on a new drug have been submitted, their use by a national health authority to study and approve a subsequent application on the basis of similarity, does not entail a violation of the confidentiality obligation under the Agreement".

Impact of Providing for Data Exclusivity

- **Allows MNCs monopoly power even in situations where a country is not required to provide patent protection, viz. LDCs**
- **Data Exclusivity allows companies to have a "patent like" monopoly for a certain period – usually at least 5 years.**
- **While 5 years may seem a small period compared to the patent period of 20 years mandated by TRIPS -- data exclusivity comes after marketing approval, i.e. usually after 5-7 years of the filing of a patent.**
- **Covers up to half or more of a patent period, and importantly, it covers the period when the benefits of monopoly protections are maximum.**

Impact of Providing for Data Exclusivity

- US is also pressing for Data Exclusivity for the new use of an existing drug, which can push the monopoly enjoyed by the originator company beyond the 20 year patent period if the new use is "discovered" just when a patent is about to expire.

Impact of Providing for Data Exclusivity

- In countries (viz. India) which have to provide Patent on Pharmaceutical Products, instrument available to curb the monopoly of MNCs is the use of a compulsory license -- a license that the Government can issue after 3 years of patent grant, if it is found that the Patented drug is not available, or it is too expensive, or the development of domestic industry or an expert market is hampered.

Impact of Providing for Data Exclusivity

- If Data Exclusivity allowed , compulsory license would be useless as regulatory authoritiesw would insist that Indian companies conduct fresh clinical trials before getting marketing approval.
- Such trials are expensive and would add to the cost of the drug, and would be time consuming and delay the introduction of the drug.
- Most importantly such trials would be unethical -- if we know that a drug is useful and it is safe, to conduct the trials again on human beings is not ethical.

World Intellectual Property Organisation

TWO Perceptions:

- **Developed Countries Pressing for Substantive Patent Law Treat (SPLT)**
- **Seeks to Harmonise Patent Laws across the world**
- **Would make TRIPS infructuous**
- **Developing Countries Pressing for "Development Agenda" in WIPO**
- **Requires WIPO to play the role of an UN body in interpreting TRIPS obligations to the benefit of countries**
- **Requires that assessment be made of country situations for determining best suited IP Laws that contribute to the country's economic and technological development**

Free Trade Agreements

- Concerned with those between Developed and Developing Countries
- US has signed (or in process) of several such FTAs
- ALL have consequences for IP Protections

Require:

- Data Exclusivity
- Broader Definition of Patentatbility
- Restriction on Flexibilities

i.e. TRIPS + + Measures