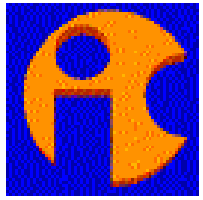

Superintendencia de Industria y Comercio

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

Topic 12: What are Grounds for the Grant of a Compulsory License?

Bogota, Colombia
February 6 to 8, 2012

WIPO Regional Seminar
Implementation and Use of Patent Flexibilities
Bogotá, 6-8 February 2012

Compulsory Licensing under the TRIPS Agreement

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I.

“Standard” Compulsory Licences under Article 31 TRIPS

Meaning of CL

- Term used in Paris Convention, but not in TRIPS
- Understood as covering a government licence that authorizes production, importation, sale or use of patent-protected product/process without consent of patent owner, granted:
  - either to a third party for its own use;
  - or for use by or behalf of government

Grounds for CL: Legislative History

- Restricted list of grounds appeared in July 1990 draft:
  - to remedy anti-competitive practices
  - to address national emergency
  - to protect public interest
  - to allow exploitation of dependent patent
  - to address failure to work
- List was not retained in final agreement
- Instead: TRIPS sets conditions for grant of CL to protect legitimate interests of right holder

Indication of Possible Grounds in TRIPS

- By reference to Paris Convention (here: Art.5(A)): prevention of abuse of IPRs, for example failure to work
  - DS 199 (US-Brazil): local working requirement in Brazil's Industrial Property Law
- In Article 31: situations of extreme urgency / public non-commercial use / anti-competitive practices / exploitation of dependent patents – but: primarily linked to waiving certain conditions for grant of CL
- In Article 8: protection of public health and nutrition, promotion of public interest, abuse of IPRs

TRIPS Does Not…

- Establish an exhaustive list
  - exception: in semi-conductor technology, grounds are limited to public non-commercial use and to remedy anti-competitive practices
- Limit grounds for CL in general
- Limit grounds to emergency situations in particular

→ **Flexibility for domestic implementation and use**

Later Instruments

- **Clarification/confirmation by Doha Declaration on TRIPS and Public Health:**
  - **compulsory licences:**
    - **right to grant CL**
    - **freedom to determine grounds**
  - **emergency situations:**
    - **right to determine what constitutes a national emergency or other circumstance of extreme urgency**
  - **application to all fields of technology ?**
- **Limitation of grounds for grant of CL in some RTAs (US-Australia, US-Singapore, US-Jordan)**

II.

Implementation and Use At National Level

Grounds Commonly Found in National Law

- Prevention of abuse of exclusive rights (including non-working, insufficient working, excessive prices)
- Safeguard of public interest (health, environment, economic development, national security, situations of emergency)
- Dependent patents, i.e. to permit exploitation of second patent which can only be done by infringing first patent

Grounds Referred to in Practice: Examples in Pharmaceutical Sector

- **Public non-commercial use**
  - Ecuador (2010 for ritonavir)
  - Brazil (2007 for efavirenz)
  - Thailand (2006-2008 for seven HIV/AIDS/heart disease and cancer drugs)
- **Public interest**
  - Declaration of public interest rejected in Colombia (2009 for lopinavir/ritonavir), instead: application of price control measures
- **Anti-competitive practices:**
  - Italy (2005-2007 for refusal to licence)

Impact of CLs (1): Examples in Pharmaceutical Sector

- **Brazil:**
  - price reduction (from US$1.59 to US$0.43)
  - first import from India, followed by local production after two years (argument: lack of sufficient disclosure)
- **Ecuador:**
  - price reduction (from US$1000 to US$800 initially; 50% reduction anticipated)
  - import from India
- **Thailand:**
  - price reduction (3.4 to 6.4 fold for efavirenz and ritonavir)
  - GPO could not ensure local production of high quality products – import from India

Impact of CLs (2): Questions and Material

- A sustainable long term solution ?
  - complex technologies
  - lack of co-operation with right holder
  - negotiating tool
  - patent flexibilities = CL ?
- Useful sources of information
  - legislative measures: notifications to TRIPS Council
  - record of TRIPS Council meetings: regular meetings and annual review of functioning of Paragraph 6 System
  - trade policy review

III.

Paragraph 6 System: An Additional Flexibility to Make Effective Use of Compulsory Licences

p.m.: Paragraph 6 Doha Declaration

- *Recognizes* that Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPS
- *Instructs* the TRIPS Council to find an expeditious solution and report to the General Council before the end of 2002

⇒ *reference to "Paragraph 6 System"*

p.m.: Issue & Solution

- Members can issue compulsory licences for importation / domestic production
- Availability of supply from generic producers in third countries ?
  - Art. 31(f) requires production under compulsory licenses "**predominantly for the supply of the domestic market of the Member**“
    ⇒ ***need to address legal problem resulting from Art.31(f) conditions in exporting Member***
- Solution: GC decisions of 2003/2005 and Protocol Amending TRIPS provide for certain derogations

First Derogation: Compulsory Licence to Produce for Export

- Basic rule under Article 31(f): production under compulsory licence predominantly for supply of domestic market
- Paragraph 6 System waives requirement for exporting Members in cases of production/export of a pharmaceutical product to eligible importing Members
- Subject to conditions on transparency and safeguards

Second Derogation: No Double Remuneration

- **Basic rule under Article 31(h): remuneration to be paid where compulsory licence is granted**
- **Under Paragraph 6 System:**
  - **Exporting Member: adequate remuneration is to be paid taking into account the economic value of the authorization in the importing Member**
  - **Importing Member: Article 31 h) is waived; no remuneration payable if paid in exporting Member for the same products**

Chairman's Statement 2003/2005

- **Represents key shared understandings of Members:**
  - **Good faith use of the system:**
    - **Health vs. commercial/industrial policy objectives**
  - **All reasonable measures to prevent diversion**
  - **Information on manufacturing capacities ("*how*")**
  - **Expeditious review in TRIPS Council and good offices of DG or Chair of TRIPS Council**
  - **List of voluntary partial/full opt-out countries**

Use of Paragraph 6 System

- Example of Rwanda / Canada
- Functioning of the System: is it delivering effective and expeditious results ?
  - TRIPS Council looks into narrow and broader aspects (see annual reviews 2010-2011)
  - Concerns expressed:
    - Too complex and bureaucratic
    - Limited number of acceptances of the Protocol
  - Others argue that:
    - Rwanda/Canada example shows that System can work
    - Less need to use System due to other measures enhancing access to medicines
- Procedural aspects: the most appropriate way forward

Acceptance of the Protocol

- **Submitted to Members for acceptance**
  - **How to accept the Protocol depends on domestic constitutional requirements**
  - **Notification of instrument of acceptance to WTO needs to respect certain procedural requirements**
- **Period for acceptance runs until end 2013 (can be further extended if necessary)**
- **Takes effect upon acceptance by two thirds of membership**
- **Limited acceptance in the region so far (by El Salvador, Mexico, Brazil, Colombia, Nicaragua, Argentina, Panama, Costa Rica, Honduras)**

⇒ ***Para.6 System under August 2003 Decision continues to apply until entry into force of amendment in a Member***

⇒ ***Distinct from implementation of Paragraph 6 System***

Paragraph 6 …

- Is an additional flexibility made available to Members
- Has to be seen in broader context, as part of wider national/international action (Doha Declaration)
- Is applicable to narrowly defined situations
  - Para.6 was never designed to and will never address all problems in the field of public health
- Facilitates imports of medicines produced under compulsory licence elsewhere
  - Para.6 is primarily not about local production
- Is it also another ground for CL ?