



TRIPS Post-Grant Flexibilities:
**Compulsory Licenses &
Government Use**

Workshop on
Flexibilities in International Intellectual Property Rules
and Local Production of Pharmaceuticals for the
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Overview of Presentation

1. Definition of Non-voluntary License
2. Grounds for Granting Compulsory Licenses
3. TRIPS Requirements
4. 2003 WTO Paragraph 6 Decision
5. Conclusions





1. Non-voluntary Licenses - I

- Authorization to use a patent **without** the **consent** of the patent right holder
- Granted by a competent authority (government or a court)
- To a government agency or a private party
- Rationale: public interest in broader access to patented invention > private commercial interest



Patentee is forced to tolerate, against his will, the exploitation of his invention by the designated person



1. Non-voluntary Licenses - II

- Crucial element in a health-sensitive patent law
- Important instrument to promote a wider availability of medicines at affordable prices
 - Price reduction by patent holder himself/ herself (threat)
 - Competition between patentee and compulsory licensee
- Establishment of a pharmaceutical industry (Canada)
- Competitiveness of the local industry in regional market where patent has expired (Italy against Merck (2005 and 2007))





2. Grounds for Granting Compulsory Licenses - I

- No limitation of grounds under Article 31 TRIPS
- Freedom to determine grounds for granting c.l. in domestic patent laws
- Different types of c.l widely recognized around the world:
 1. Exploitation of patent right **violates competition law**
 2. Patentee **abuses** his/ her exclusive right (less than competition law violations)/Excessive prices





2. Grounds for Granting Compulsory Licenses - II

3. Market demand not sufficiently satisfied
4. Public interest (e.g. health, environment, economic development/defense or development of vital sector an economy, national security)
5. Dependent patents (technical improvement; use of dominant invention)
6. Government non-commercial use





Article 8 : Members may adopt measures necessary

- to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development,
- to prevent the abuse of IP rights or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.





- All Sub-Saharan Africa countries have laws permitting c.l
- Failure to work or insufficient working and failure to supply the domestic market sufficiently are grounds that appear widely across the laws.
- Angola, Liberia, Mauritius, Mozambique, Nigeria, Tanzania, Uganda, Bangui agreement also recognise the development of vital sectors of the economy as grounds for c.l



3. TRIPS Minimum Standards : Substantive Requirements - I

1. Authorization on a case by case basis
2. Prior unsuccessful negotiations with patentee a reasonable period of time and on reasonable commercial terms and conditions
 - Exceptions
 - (1) [Officially declared] national emergency or other situations of extreme urgency
 - (2) Government/ public non-commercial use – provided that the right holder is informed promptly
 - (3) Remedy to anti-competitive practices





Unreasonable commercial terms and conditions

□ Examples:

- High amount of **royalty** payable to patentee (varies from industry to industry, depends on market value of technology at issue)
- Unreasonably short **duration** of voluntary license
- **Non-disclosure** of patentee's knowledge needed to work the patent
- **Grant back** any improvements made on licensed technology
- **Export restrictions** preventing licensee from realizing economies of scale



Reasonable period of time

- No fixed time frame
- Depending on purpose of the licensed activity and urgency of access to licensed products -> shorter period of time in case of production of life-saving drugs than in case of production of luxury goods
- Public health issue: maximum 90 days;
- Canadian legislation on humanitarian supply of medicine -30 days.





3. Payment of adequate remuneration

➤ Applicable to both c.l. and government use

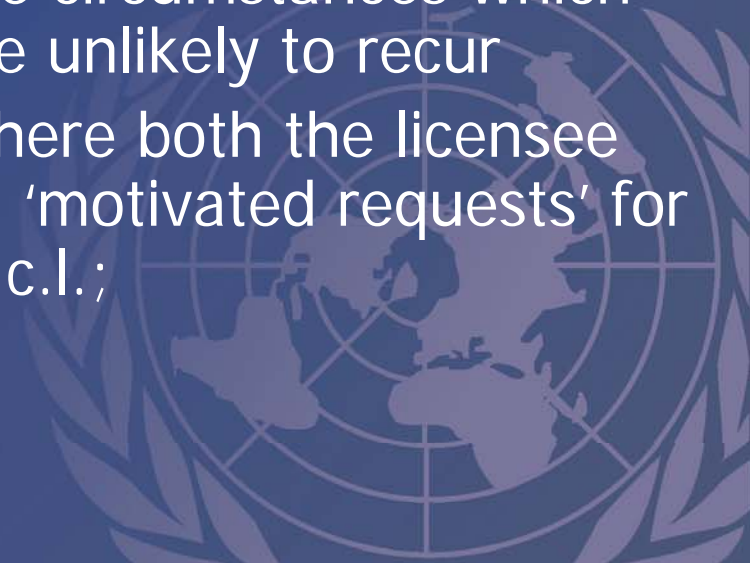
What is adequate?

- ❑ Discretion of authority granting the c.l.;
- ❑ Marginal costs of production + certain percentage of compulsory licensee's selling price
- ❑ **5 % reference rate** with possibility of reducing/increasing rate, depending on **case-by-case** considerations
- ❑ **In case of public health the practice is for less than 1%, for competition it could be as low as 0%**
- ❑ **Indicators** for guidance: Economic value of the compulsory license;
 - Government funding
 - Remedy to anti-competitive behavior
- ❑ Burden of proof on patentee challenging decision



4. Scope and duration of compulsory license

- a. The license can cover the product and process, trade secret, know-how and technology (but not trademark)
- b. Non-assignable (but selling and transferring of business allowed)
- c. Non-exclusive (competition)
- d. Be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur
- e. Include review mechanism where both the licensee and the patentee may submit 'motivated requests' for the (dis-) continuation of the c.l.;





5. Review by judicial or higher authority

- Appeal matters:
 - Authorization of a c.I. itself (could be limited to 'declaratory judgment')
 - Amount of remuneration
- Appeal **authority**: independent and higher than initial granting authority-court or independent government entity;
- **No injunctive relief** against the grant of a c.I./government use





6. Must be *predominantly for* or the supply of the domestic market





4. 2003 WTO Paragraph 6 Decision - I

- Doha Declaration on the TRIPS Agreement and Public Health (para. 6) calls for a solution for countries with insufficient or no manufacturing capacities
- WTO General Council (August 2003) established the system for production of pharmaceuticals produced under compulsory license for export
- Protocol for the Amendment of the TRIPS Agreement 2005 (*Article 31^{bis}*) -2005





4. 2003 WTO Paragraph 6 Decision - II

Exporting Country issue authorization for export of **entirety** of production of medicines but only to countries with insufficient domestic pharmaceutical manufacturing capacities (**export c.l.**)

- **Medicine;**
- **Active pharmaceutical ingredients;**
- diagnostic kits needed for the use of the product





- Importing country issue authorization for import of medicines
- Eligible importing member states (import c.i.) is defined based on insufficient /no domestic manufacturing capacities, with respect the product to be imported:
 - Technical capability (trained personnel, equipment, access to raw materials)
 - Economic feasibility of production





4. 2003 WTO Paragraph 6 Decision - III

The use of the System:

- *General Notification:*
 - All developing countries that intends to use the system has to notify the WTO – no country has made such notification to date;
 - LDCs are not required to make such notification
- *Specific Notification:*
 - exporting and importing developing countries, and LDCs need to notify each case of the use of the system (Canada & Rwanda);





- The developing importing countries also need to
 - establish that they have insufficient or no manufacturing capacity for the medicine covered;
 - Whether there are patents and it intends to issue compulsory license;
 - the names and expected quantities of the product(s) needed;
 - No remuneration in importing country





Exporting country and supplier (beneficiary of c.i.)

- Medicine to be exported is patented in exporting country , and c.i. is granted
- the amount necessary to meet the needs of the importing country
- labelling or marking, special packaging/ colouring/ shaping
- Notification by supplier about quantities to be supplied to each destination, distinguishing features of the product (website)
- Adequate remuneration





Regional cooperation

Within regional trade agreement composed of at least 50 % LDC members

- **(Re-) export** of pharmaceuticals imported or produced under system without additional WTO notifications to all other developing country or LDC parties to the trade agreement sharing the same health problem at issue

! **National c.I.** for importation has to be issued in each importing country as long as no regional patents are recognized





6. Conclusions

1. Public and private commercial interests must be balanced thoroughly
2. Provide for compulsory licensing provisions in your patent law
3. Determine broad (health related) grounds for issuing c.l.
4. But also consider alternative means to improve access to medicines (pre-grant flexibilities, price regulation)



Thank you for your attention

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