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

Topic 8: Compulsory Licenses

Durban, South Africa
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WTO-DTI Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities

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The TRIPS Agreement and compulsory licenses

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Outline

- The “life” of a patented invention
- Article 31 TRIPS in general
  - The approach of conditions versus grounds for compulsory licenses (CL)
  - Different types of use without authorization
  - Rules for a “common CL”
- Article 31 TRIPS and public health
  - Doha Declaration on TRIPS-public health
  - Paragraph 6 system

The “life” of a patented invention

- The *normal* and ideal “life” of a patented invention or how a company usually proceeds (very simplified presentation):
  - Invention: is it patentable?
  - Application: rules to be fulfilled (important to disclose (dissemination of knowledge: Art. 7 objective (“social deal”)
  - Steps of procedure, depending on system adopted
  - Grant of patent

  (balance of interests with safeguards normally)

The “life” of a patented invention

- What could the patent owner do:
  1. Work it himself?
  2. Sell it?
  3. Licence it?
- Voluntary licence
  - ideal because non-conflictual
  - Know-how ideally with patented invention (technology transfer scenario)
  - Negotiating power

  [see Art. 40 and delegates’ slides)
- BUT, what if things do not work that way?

“Use without authorization”

- The approach of the TRIPS Agreement:
  - Too difficult to agree on all the various existing systems or that there should be only one or two categories:
    - Public non-commercial use (“Government use”)
    - Compulsory licences (or non-voluntary licences): existing systems of CL for public interest, licences of right, CL for non-working or insufficient working, for anti-competitive practices)
    - Dependent licenses (for dependent inventions)

“Use without authorization”

- So, better focus on the conditions of use without the patentee’s authorization (because certain situations require different conditions, certain grounds have to be mentioned, e.g. Emergency, anti-trust, etc.).
- Misunderstanding of some circles, inclduing governments , that Art. 31 has limited precise grounds

Article 31

In a nutshell:

- TRIPS does not:
  - establish an exhaustive list
  - limit grounds for CL in general
  - limit grounds to emergency situations in particular
- TRIPS does:
  - indicate possible grounds for CL (Art.31, 8, reference to Paris Conv.)
  - set conditions for grant of CL - see Article 31

→ Flexibility for domestic implementation & use

→ Clarification/confirmation by Doha Declaration

Compulsory licences under Article 31

- Conditions for the grant of a compulsory licence
  - Individual merits
  - Unsuccessful efforts to obtain a voluntary license on reasonable commercial terms and conditions within a reasonable period of time.
    - **except in cases of national emergency or other circumstances of extreme urgency or public non-commercial use**
  - Scope and duration to be limited to the purpose for which it was authorised.
  - Non-exclusive

Compulsory licences under Article 31

- Non-assignable, except with that part of the enterprise or goodwill
- **Predominantly for the supply of the domestic market (letter(f))**
- To be liable to termination if and when the certain circumstances cease to exist and are unlikely to recur.
- **Adequate remuneration to the right owner**
- Judicial review of the decision relating to the grant and remuneration

Some uses without authorization under Article 31

- Examples in area of pharmaceuticals. Why? The economics of pharmaceutical patents
- See WHO's and delegates' slides in Durban too
- 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
  - India (2012 for sorafenib)
  - 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)

Impacts on pharmaceutical area?

- Price reductions
- Imports of lower priced drugs, etc.

- BUT, is it a sustainable long term solution ? Different views
  - complex technologies
  - lack of co-operation with patent right holder
  - Case of India = exceptional case because size of market, long-time experience

Why a Doha Declaration on TRIPS-public health?

- Separate Ministerial Declaration in WT/MIN(01)/DEC/2).
- Why?
  - Fears of some quarters and governments of using certain flexibilities.
- The Doha declaration reaffirms or clarifies, inter alia:
  - Balance of interests for the society (access to medicines (price) and R&D
  - Art.7 and 8
  - The flexibilities, e.g. on
    - Right to chose exhaustion régimes
    - Issues of national emergency, extreme urgency
- Transition period for LDCs for pharmaceuticals (2016

See WIPO's and delegates' slides

The “Paragraph 6 System”

But also

- *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”*

Article 31(f) issue

- 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: three waivers (derogations), adopted in light of Chair’ statements

The 1st waiver

- 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

The 2nd waiver

- 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 (n.b.: unless treaties are directly applicable, this requires a change in legislation/regulation)

The 3rd waiver

- **Concerns: Regional trade agreements**
- **Objective: economies of scale, enhance purchasing power, help local production**
- Derogation from Art. 31(f) if:
  - RTA falls within WTO rules
  - At least half of the RTA members are LDCs
  - Members concerned share the health problem in question

  ⇒ *Note: derogation does not affect any patent status in importing countries - principle of territoriality*
- Promotion of regional patent systems
- Developed countries, in conjunction with IGOs, to provide technical cooperation

The “Paragraph 6 System”

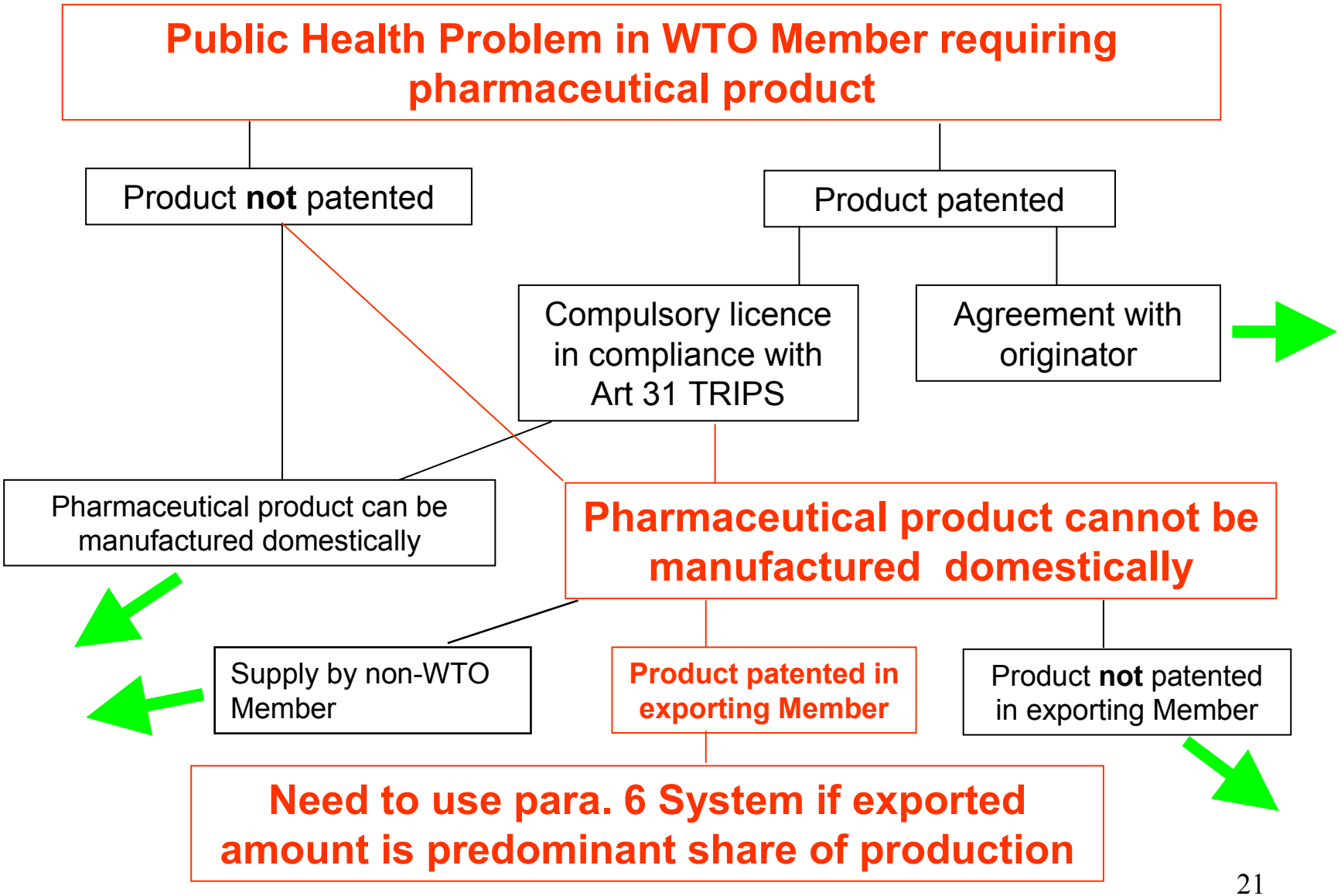
- General Council Decision of 30 August 2003:
  - contains three waivers (derogations)
  - in effect since 30 August 2003, **terminates when amendment replaces it for each Member**
- GC Decision of 6 December 2005 / Protocol Amending TRIPS proposes insertion of:
  - new Article 31*bis* consisting of 3 waiver provisions of August 2003 Decision
  - Annex setting out terms for using Paragraph 6 system
  - Appendix to Annex dealing with assessment of manufacturing capacities (former annex to August 2003 Decision)

  ⇒ *“technical exercise”, no changes in substance to Paragraph 6 System*

TRIPS-Public Health in sum

- Heavily negotiated
- Doha Declaration
  - Confirmation of importance of R&D and innovation but also **flexibilities**
  - Transition period for least developed countries (LDCs)
  - Paragraph 6
- Article 31; Article 31(f)
- Paragraph 6 system is meant to address a *health* problem in the importing Member and a *legal* problem in the exporting Member. **Not purported to resolve all public health problems**

When to Use the Para.6 System



One of the «best practices»

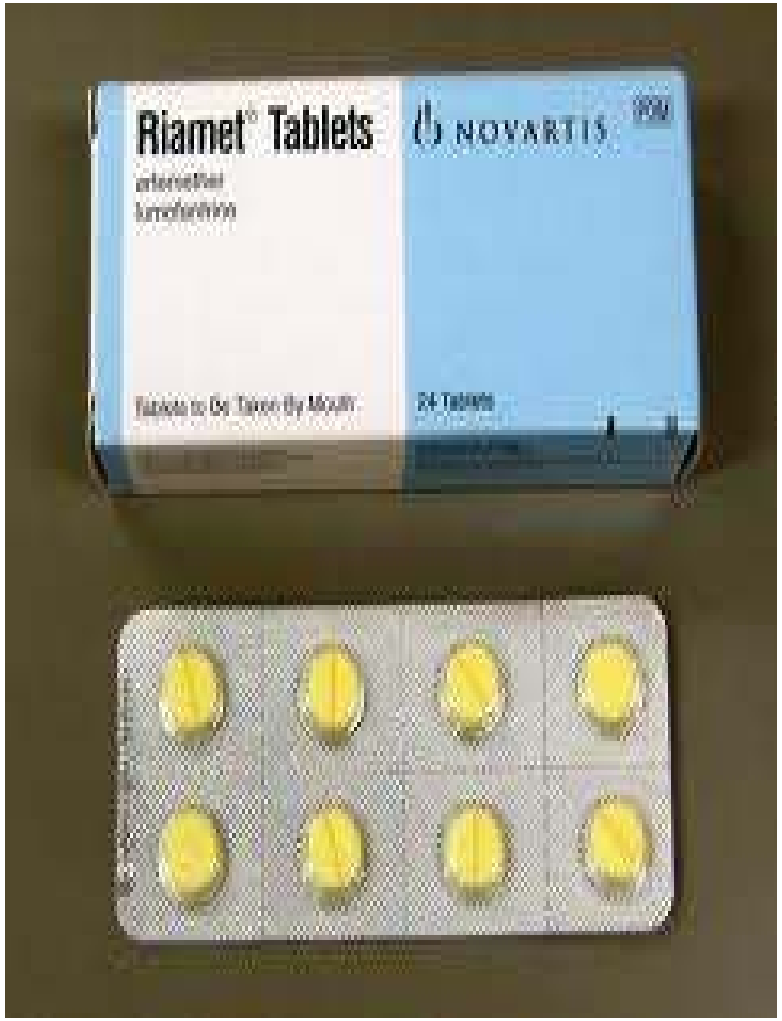


Image used for teaching only (TLTW)

TRIPS-Public Health - Some References

- Doha Declaration on TRIPS and Public Health (WT/MIN(01)/DEC/2)
- Decision on the implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health (WT/L/540 and Corr.1)
- Decision on an amendment to the TRIPS Agreement (Protocol) (WT/L/641)
- Annual Review of the Functioning of the System 2010 (IP/C/57 and Corr.1)
- Members' laws implementing the Para.6 System: http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm
- How to accept the Protocol Amending TRIPS: http://www.wto.org/english/tratop_e/trips_e/accept_e.htm
- Decision on extension of transition period for LDCs with respect to pharmaceutical products (IP/C/25)
- Decision on general extension of transition period for LDCs (IP/C/40) - June 2013, being discussed /negotiated at the time of Durban's workshop

Some remarks (1)

- CL may help resolve but is not the panacea.
- Need for R&D of new molecules and need for affordable medicines
- Negotiating power and importance of dialogue
  - national task forces
  - At regional and international levels
- Importance of Doha Declaration
- Use of flexibilities in a manner which does not end up being counter-productive or inefficient

Some remarks (2)

- Application of Paragraph 6 System so far
  - Rwanda – Canada
- Paragraph 6 System and acceptances: not many acceptances from countries of the African Continent
  - At the time of Durban WIPO-DTI seminar: (in chronological order), following participating countries: Mauritius, Zambia, Uganda, Rwanda, Togo
- Different views on the Paragraph 6 System:
  - Very complex and bureaucratic
  - Flexibilities used, plus voluntary actions by companies

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Consult our website

www.wto.org

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