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

Topic 8: Compulsory Licenses
The TRIPS Agreement and compulsory licenses

Thu-Lang TRAN WASESCHA
Counsellor, Intellectual Property Division
WTO Secretariat

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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, including 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)
• 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
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 2\textsuperscript{nd} 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, \textit{terminates when amendment replaces it for each Member}

• GC Decision of 6 December 2005 / Protocol Amending TRIPS proposes insertion of:
  – new Article 31\textit{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)

$\Rightarrow$ “\textit{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

Public Health Problem in WTO Member requiring pharmaceutical product

Product not patented
- Pharmaceutical product can be manufactured domestically
- Supply by non-WTO Member

Product patented
- Compulsory licence in compliance with Art 31 TRIPS
- Agreement with originator

Pharmaceutical product cannot be manufactured domestically
- Product patented in exporting Member
- Product not patented in exporting Member

Need to use para. 6 System if exported amount is predominant share of production
One of the «best practices»
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)
- 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
Consult our website

www.wto.org

Other questions to:

n thu-lang.tranwasescha@wto.org; tel.: +41 22 739 57 05; # 3024