

# **New Trends in Multilateral IP Policy Making: The suspension of the WTO negotiations and the debate on the WIPO Development**

Recent Trends in Multilateral and Bilateral in IP Policy Making  
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# Paradigm: Inclusion of IPRs in the Multilateral Trading System (WTO)

- TRIPS Agreement signed a major change in international economic relations:
  - Integration of IPRs with the multilateral trade regime
  - Since US 1974 Trade Act link between adequate IPR protection and trade was established, but there was no consensus at the international level
  - Developing countries were concerned about their own development
    - ✓ Claimed transfer of technology as a needed mean for development
    - ✓ Risk of being obliged to patent inventions related to public health and nutrition (UNCTAD, 70's)

# Structure of the TRIPS Agreement

- **PART I – GENERAL PROVISIONS AND BASIC PRINCIPLES**
- **PART II – STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS**
  1. Copyright and Related Rights;
  2. Trademarks;
  3. Geographical Indications;
  4. Industrial Design;
  5. Patents;
  6. Lay-Out Designs (Topographies) of Integrated Circuits;
  7. Protection of Undisclosed Information; and
  8. Control of Anticompetitive Practices in Contractual Licenses
- **PART III – ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS**
  1. General Obligations;
  2. Civil and Administrative Procedures and Remedies;
  3. Provisional Measures;
  4. Special Requirements Related to Border Measures; e
  5. Criminal Procedures.
- **PART IV – ACQUISITION AND MAINTENANCE OF INTELLECTUAL PROPERTY RIGHTS AND RELATED INTER-PARTES PROCEDURES**
- **PART V – DISPUTE PREVENTION AND SETTLEMENT**
- **PART VI – TRANSITIONAL ARRANGEMENTS**
- **PART VII – INSTITUTIONAL ARRANGEMENTS: FINAL PROVISIONS**



# TRIPS' Effects (in practice...)

- Developing countries point costs and burdens created due to TRIPS, such as:
  - ✓ Patents: Ex.: requirement of patenting all products (including drugs), extension of term of duration
  - ✓ Other issues: database, software, data exclusivity
  - ✓ Effects on royalties, prices and implementation
- Pre-TRIPS, many countries did not grant patents for drugs
  - Impact on dynamic efficiency/competition
  - Effects on access and prices

# TRIPS: Principles and Objectives

- Reduce distortions and impediments to trade: IPRs are not to be used as (non-tariff) barriers to trade
- Balance in-built in the Agreement: protection of IPRs owners with economic and social welfare, as well as with technological development

“Members may, in formulating or amending their laws and regulations, **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, provided that such measures are consistent with the provisions of this Agreement.”

# TRIPS' Flexibilities

- Need to explore and use flexibilities that are in-built in the TRIPS agreement
- Procedure of implementing and interpreting the TRIPS Agreement is required to balance rights and obligations
  - TRIPS, as all WTO Agreements, was written with “diplomatic” language (vague and not precise): space for interpretation

# TRIPS Flexibilities

TRIPS contemplates flexibilities and safeguards:

- Compulsory license (art. 31)
- Exhaustion of rights and parallel imports (art. 6)
- Exceptions to rights conferred (art. 30)
- Control of anti-competitive practices in contractual licences (art. 40)
- Implementation deadlines (art. 64)
- Limitation of dispute settlement cases (exclusion of “non-violation” and “situation”) (article 64,2)
- Definition of patentable subject matter and patentability of living things (art. 27 and art. 27,III.b)

# TRIPs Implementation

- Implementation of TRIPS Agreement at:
    - ✓ TRIPS Council (WTO Members Meetings)
    - ✓ WTO Ministerial Conferences
    - ✓ Decisions of the Dispute Settlement Body
  - Developing Countries have been claiming the need to re-balance the Agreement
    - ✓ Doha Declaration on TRIPS and Public Health (2001)
    - ✓ General Council Decision of August 30, 2003.
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# Declaration on the TRIPS Agreement and public health (Doha, 2001)

- WTO Members recognized:
  - ✓ the gravity of the public health problems afflicting many developing and least-developed countries;
  - ✓ stressed the need for the TRIPS Agreement to be part of the *wider action* to address those problems;
  - ✓ that even though intellectual property protection is important for the development of new medicines, it has effects on prices.
- Least-developed countries were given a waiver, until 1 January 2016, regarding the obligation of patenting pharmaceuticals

(WT/MIN(01)/DEC/2, Doha, 20-11-01).

# Declaration on the TRIPS Agreement and public health (Doha, 2001)

“4. We [WTO Members] agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.

Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

(WT/MIN(01)/DEC/2, Doha, 20-11-01)

# WTO General Council Decision of August 30, 2003

- August 2003 (Pre-Cancun Ministerial Conference): a Decision from WTO General Council removed patent obstacle to cheap drug imports
- WTO Members agreed on legal changes that should make it easier for poorer countries to import cheaper generics made under compulsory licensing, if they are unable to manufacture the medicines themselves.

(Decision of General Council of August 30, 2003, WT/L/540)

# WTO: the suspension of the Doha Round and the TRIPS Council fora

- Doha Development Round suspended in 2006
- Issues on the TRIPS Council agenda will remain being discussed and attention should be devoted to it
- DSB/Non-violation (in-built revision of art. 65)
- Compatibility of TRIPS (art. 27,III (b) with Biodiversity Convention

# What about TRIPS-plus standards?

- Implementation and interpretation of TRIPS should guarantee that flexibilities are maintained
  - In decision of the DSB: importance of active participation (even as Third Party)
  - In other regional and bilateral trade negotiations
    - ✓ US has already achieved TRIPS-plus standards in other regional and bilateral agreements (Singapore, Australia, Chile, Jordan, CAFTA, Morocco and Bahrain)
- By means of (TRIPS-plus) harmonization
  - ✓ Substantive Patent Law Treaty, Broadcasting Agreements, DCMA, technical cooperation etc...

# RTAs Negotiations and TRIPS-plus standards

- RTAs usually have IP chapters, normally with TRIPS-plus standards:
  - ✓ Requirement to be part of other international treaties
  - ✓ Definition of “patentable subject matter” (Ex.: plants and other living things, second use of known compound etc.)
  - ✓ Extension of patent term under certain conditions
  - ✓ Strict rules for compulsory license and data exclusivity
  - ✓ Provisions on “certain regulated products” (pharmaceutical and agricultural chemical)
  - ✓ Provisions securing periods for market exclusivity for patentable and non-patentable products
- Once the standard has increased in a bilateral Agreement, there is no reason for such country not entering into others<sub>14</sub>

# The World Intellectual Property Organization (WIPO) Arena

- WIPO was created back in 1967 - as a UN Organization - to administer the international intellectual property treaties and, pursuant to the TRIPS Agreement, WIPO should develop an important capacity building role
- Besides providing technical assistance for Member countries, among others WIPO has been the fora for the negotiation of new treaties, such as the Substantive Patent Law Treaty (SPLT) and broadcasting treaties
- Developing countries point that WIPO has been leading to “soft harmonization” to a TRIPS-Plus standard
  - Technical assistance programs were harmonizing legislations according to development countries standards
  - New treaties follow developed countries interests

# WIPO Development Agenda

- Brazil and Argentina presented a document at WIPO (November 2004) claiming that WIPO - as UN Agency - was not working according to the Millennium Development Agenda goal:
  - Capacity building and transfer of technology as core issues
  - WIPO should be an adequate forum for this purpose
- In April 2005, other developing countries joined the claim and the topic is currently being discussed at WIPO

# Conclusion Remarks

- Scenario might have changed a bit, but challenges for developing countries remain similar:
  - Build capacity
  - Assess impacts of commitments
  - Use TRIPS flexibilities
  - Prevent TRIPS-plus standards

# Thank you

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Society has very different interests in inventions depending on their field of use. From the standpoint of IPRs law, this insight can be dealt with in a number of ways. It can be approached from the standpoint of (a) exceptions to the grant of IPRs, (b) variations in the terms of the grant of IPRs, and (c) variations in the scope of regulatory authority with respect to the use of IPRs.

The second basic principle is that all levels of development are not equal. Countries at different stages of economic development have different interests insofar as the value to society of protecting IPRs is concerned. If encouraging development is a high priority of the WTO, more leeway for use of technology by developing countries would likely benefit those countries.

The problem set is how to encourage local developmental uses of technology without undermining innovation in the developed countries. The TRIPS

# RTAs Negotiations and TRIPS-plus standards

- US-Chile Agreement, for instance, adopted TRIPS-plus standards on the health area and expanded protection for pharmaceutical products
  - ✓ Reinforced the provisions on marketing and sanitary approvals
  - ✓ Required the adjustment of the term of the patent to compensate for unreasonable delays in granting the patent and/or marketing approval
  - ✓ Prohibition of use of undisclosed information from five years from the date of its governmental approval
  - ✓ Granting marketing approval to third parties requires consent of patent owner

ROFFE, "The US-Chile FTA: Intellectual Property Issues", *Bridges*, vol. 7, 2004, pp. 17-18