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Trade, Knowledge and Intellectual Property Rights Thematic Tent

REPORT

Session One

*The IPRs Chapter of the FTAA: Outlining the Development Perspective*

The FTAA Chapter on IPRs imposes the following challenges:

- Includes commitments that go beyond what is already included or consolidated in the minimum standards of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (referred to as TRIPS plus). Many Latin American countries are still trying to implement TRIPS.
- It expands the protection on subject matter and periods of protection to US levels and in some areas beyond US standards (referred to as US-plus) and includes WIPO new WIPO treaties to adhere to or ratify that not all current FTAA member countries have signed on to or agree with.
- The MFN clause contained in Article 4 of the TRIPS agreement is very different than the MFN principle found elsewhere in the WTO resulting in higher obligations automatically becoming multilateralised and is used as a tool to spread higher IPRs standards in bilateral and regional agreements.
- “Trade-offs” made in the TRIPS Agreement during the Uruguay Round were not given sufficient consideration. Before any more commitments are agreed to there is a need to evaluate transfer payments and copyright licensing to developed countries with the value of exports and industrial products. Currently, there are major distortions in trade in the hemisphere.
- TRIPS plus standards will mean losing existing flexibilities within TRIPS. It will be hard to regain these flexibilities. The WTO Doha Declaration on the TRIPS Agreement and Public health is an example of this.
- The negotiating process is undemocratic and non-transparent not only at the FTAA level, but also at the bilateral level. Texts are not derestricted and there is a lack of participation by all stakeholders. The TRIPS agreement minimum floor approach was rejected as it is seen only as a minimum standard upon which expansion can occur. As a result proposals submitted by Latin American countries are often not considered.
- It provides for a wide range of enforcement measures that could be distorting.

- Given existing WTO TRIPS obligations on every country in the FTAA and that the FTAA is being used as a mechanism to ratchet up IPRs standards, and it is questionable whether IPRs should continue to be negotiated in the FTAA forum.

## Session Two

### *Trading Away Health in the Free Trade Area of the Americas (FTAA) Agreement*

- There was an consensus among panellists and participants that in order to ensure that countries in the Americas can uphold their rights and obligations to protect public health and promote access to medicines for all, as per the Doha Declaration on TRIPS and Public Health, intellectual property (IP) should be excluded in the final FTAA agreement.
- Panelists focused on the example of HIV/AIDS, as the lack of access to antiretroviral (ARV) therapy is clearly a global public health emergency and is the most vivid example of the impact of patents on prices and the impact of prices on access to medicines in developing countries in the Americas and elsewhere. In Latin America and the Caribbean, there are approximately 2 million people living with HIV/AIDS, the majority of whom do not have access to ARV treatment. However, the impact of proposed IP provisions in the FTAA are not just related to HIV/AIDS but rather all new medicines for all diseases affecting people in the region – from neglected tropical diseases like Chagas and malaria to conditions affecting both rich and poor throughout the hemisphere.
- IP provisions in the current draft FTAA text, which are clearly “TRIPS-plus,” will threaten access to medicines by restricting generic competition, the most powerful, reliable force for bringing the prices of medicines down (in the case of ARVs for the treatment of HIV/AIDS, this has lead to drops in prices from over \$10,000 per person per year to less than \$300). This dynamic allows limited public health budgets to reach the largest number of people possible who require the treatment.
- IP proposals in the current text, which correspond with the negotiating objectives of the United States, will limit generic competition by restricting the grounds on which compulsory licenses may be issued; extending patent terms beyond the 20-year minimum established in TRIPS; artificially linking patent status to drug registration by requiring drug regulatory authorities to consider patent status before granting marketing approval to generic manufacturers; granting exclusive rights on pharmaceutical test data needed to demonstrate safety and efficacy, which will delay generic competition for five years even where there are no patent barriers; restrict parallel importation to the FTAA region; and prohibit exports of medicines produced under a compulsory license.
- Panelists gave many examples of the dangers of these provisions, and the concrete impact they will have on access to medicines in the Americas from Guatemala, Costa Rica, and Brazil. Data exclusivity clauses, already enacted in Guatemala for example, have caused the ministry of health to radically reduce the number of drugs registered for fear of commercial liability, and will have the effect of delaying generic competition for five years, a matter of life and death for people with HIV/AIDS. Countries like Costa Rica that have invested in a social security system that guarantees access to medicines will be heavily affected if generic competition is limited: with generics, ARVs account for 5.9% of the national budget for medicines, whereas with only brand-name drugs they would account for over 20%.
- Although the FTAA is the most far-reaching effort to undermine the Doha Declaration, it is by no means the only one. Panelists explained that the US is systematically covering the globe with bilateral, sub-regional, and regional free trade agreements—such as the US-Chile, US-Singapore, US-Thailand, US-Jordan, US-Morocco, US-Southern African Customs

Union, and US-Central American Free Trade Agreements. This strategy to establish a global “TRIPS-plus norm” isolates countries who are then more vulnerable to bilateral political pressure, and threatens to systematically restrict the ability of countries to make use of flexibilities in the TRIPS agreement, reaffirmed in the Doha Declaration.

- Panelists explained that a good IP system is not necessarily one with the highest possible levels of protection; that the access to medicines debate shows the need for national diversity that allows for the most *appropriate* levels, which may differ per country; and that the final draft of the FTAA must not renege on the historic agreement reached in Doha.
- Panelists highlighted other aspects of the FTAA agreement (such as the investment chapter) that will also affect IP and access to medicines, and identified several areas requiring further work, including the need to focus on patent abuse (not just patent protection), defining anti-competitive practices in terms of affordability and accessibility, promote technology transfer, and explore alternative paradigms for stimulating research and development (R&D).
- Regardless of the forum (national legislation, bilateral agreements, or the FTAA) countries must prioritise public health over private commercial interests and implement the TRIPS flexibilities fully.

## Session Three

### *Agriculture, Food and IPRs in the FTAA*

Intellectual property protection in agriculture has stimulated the biotech industry and corporate concentration, while inhibiting public research and development and narrowing the diversity of the gene pool. Local, national, regional, and global food security, farmers’ livelihoods and agro-ecological health are all in jeopardy as a result.

Consequently, the panel recommended that plant variety protection, for instance, take into account these social, economic, ethical, and environmental concerns. In that sense, while the TRIPS Agreement obliges WTO Members to protect plant varieties, it does allow the use of a *sui generis* system, which the panel considered crucial to adapting this protection to safeguard the interests of all stakeholders. For countries in Latin America already Members of Union for the Protection of Plant varieties (UPOV) , it was pointed out that the 1978 version contains some recognition of the challenges of plant variety protection that were lost in the 1991 version, which substantially strengthened breeders’ rights. Latin American countries should thus reject any standards in the IP *chapter* of the FTAA Agreement that seek to achieve the level of protection granted by UPOV 1991.

Another significant issue analysed by the panel was the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Its successful implementation depends to a large extent to the clarification of its relationship to IP regimes. IPRs have a crucial role to play, both for the conditions of access to plant genetics resources and the mechanisms of benefit sharing established in the facilitated multilateral system of access. Another outstanding concern in the ITPGRFA is the non-inclusion of genetic materials in the hands of the private sector, which has an adverse impact on the equity of the treaty. As a result, developing countries should strive for IPR regimes to 1) recognize and promote farmers’ rights as defined in the treaty; 2) include food security as a matter of public interest and treat it accordingly; and 3) exclude naturally occurring biological material or genetic material “as received” from IP regimes or any other form of private appropriation to protect the rights of countries over their biodiversity and the contribution of local communities to agricultural industries.

## Session Four

### *Finding Synergies in the FTAA Between the Convention of Biological Diversity and IPRs (Joint session with the trade and environment tent)*

#### Introduction

This session focused on the interface between intellectual property rights and the conservation and sustainable use of biological resources, which is addressed by a variety of international instruments, most importantly the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), the Convention on Biological Diversity (CBD), the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and the ongoing discussions in WIPO on traditional knowledge and on a new Substantive Patent Treaty.

It was noted, that so far the FTAA is the most advanced international discussion of these issues in the context of a trade agreement. In addition, some of the States involved in these negotiations have adopted advanced national legislation on ensuring that IPRs are supportive of biodiversity and protect traditional knowledge. Both these factors represent an important opportunity to ensure that the final results of the FTAA negotiations also support the global regime to conserve biodiversity, the sustainable use of biological resources, and the equitable sharing of benefits arising from access to genetic resources. Indeed, these FTAA negotiations can help trigger innovative thinking that can help break the stalemates that currently plague the negotiations at the global level, especially in the WTO.

#### **The relationship between the CBD and IPR in the light of the FTAA process**

The first presentation highlighted the relation between TRIPS and the CBD. The CBD recognises the sovereign right of countries over their biological resources. Access to and exploitation of genetic resources and related knowledge and practices are subject to prior informed consent and must give rise to equitably shared benefits. These key principles were again reiterated in the Bonn Guidelines on Access to Genetic Resources and are likely to form the basis of the international access and benefit-sharing regime to be negotiated under the auspices of the CBD as mandated by the World Summit on Sustainable Development (WSSD). The TRIPS Agreement on the other hand requires Members to grant intellectual property rights for all inventions, with some exceptions, and contains no provisions requiring prior informed consent and benefit sharing. These differences reflect the fact that, although both Agreements were practically negotiated simultaneously, different policy communities were involved in the drafting teams, often with insufficient or ineffective coordination.

In the past ten years, several developing countries, including from the Americas, have repeatedly called for a harmonisation of TRIPS and CBD within the framework of the TRIPS Agreement. Their concerns found reflection in the current Doha mandate of trade negotiations where governments agreed to explicitly include related issues of traditional knowledge protection, the TRIPS-CBD relationship and the review of Article 27.3(b) on the patentability of life forms in the Doha Ministerial Declaration.

Besides this general introduction presentations went into more depth in presenting the issue of certificates of origin; the increasing complexity of the IPR system at various levels, and the problems related to UPOV 1991.

## **IPR's Protection for Traditional Knowledge and Access to Genetic Resources**

The second presentation gave an Andean perspective to the general issues presented above on the relationship between the CBD and IPR. In highlighting the relationship between the CBD and the draft FTAA the following issues were noted:

- Reduction of patent exclusions and exceptions
- Patenting of any biological material
- Patenting of any material having the same genetic sequence
- Taking into account CBD for microorganisms
- PV protectable through UPOV and/or patents.
- PV protection to all genera and species
- Folklore: Model Law, Indication of source (citation)
- Indications of Origin: Ample definition.
- Tech Transfer: Best effort clauses

It was noted that the IPR is a defensive means of protection compared to a more positive protection regime as granted through *sui generis* protection systems. The Andean proposal to the FTAA on this topic included the following elements:

- Effective *sui generis* protection or other alternative systems to protect knowledge, innovation and traditional practices associated or not to BR or GRs.
- Country of origin's sovereign right to determine access conditions.
- PIC from the parties and their communities.
- Access compensation and equitable benefit sharing.
- Appropriate measures to guarantee compliance and other parties rights over their BR, GRs and TKs
- IPRs granting in due respect to the other parties rights (BRs, GRs and TKs and derived products)
- Patent granting subject to conformity of access with CDB, national and international legislation. Disclosure of GRs utilized, country of origin, TKs innovations and practices and their source.
- Proof of the granting of PIC
- Previous Art searches shall include information related to biological and genetic material and their derived products and TKs
- Patent examination shall consider the information sent by the other parties.

## **Recommendations and Conclusions for the FTAA**

In sum the following issues emerged from the discussions:

- Any discussions within the FTAA should not undermine current negotiations in multilateral forums such as WTO, CBD, WIPO and FAO.
- The disclosure/certificate of origin is an important tool for securing compliance with national access and benefit sharing laws and for the prevention of biopiracy. However a more comprehensive approach is required to support full synergies between the CBD and the IPR regime.

- The issues addressed in this workshop relating to Access and Benefit Sharing and Traditional Knowledge should not only be covered under Chapter 6 relating to patents of the FTAA, but adequate consideration should be given throughout the entire agreement.
- Technology Transfer should move towards implementation especially related to Access and Benefit Sharing of genetic resources.
- CBD and the new ITPGRFA principles, together with adequate legal mechanisms for assuring legal access, are incorporated
- Protection of traditional knowledge and folklore is provided and fully developed
- Flexibilities to chose and use the most convenient system to protect plan varieties through a *sui generic system*

## Session Five

### ***Access to Information and the Copyright and Related Rights Provisions in the Proposed FTAA***

Recognizing the need to maintain a balance between the rights of authors, copyright owners and the larger public interest, particularly for the purposes of education, research and access to information, we recommend that the provisions relating to copyright and related rights:

- Respect international principles and obligations including Article 19 and 27 of the Universal Declaration of Human Rights,
- Be consistent with pro-competitive approaches to copyright policy,
- Accord higher priority to the protection of personal privacy,
- Ensure access to essential research, teaching, and learning tools, and
- Not undermine the efforts of developing countries to bridge the knowledge gap.

Recognizing that innovation is essential for the information society, we recommend that;

- Trade agreements should promote and not inhibit innovation.
- The FTAA provisions on intellectual property should encourage the development of open and free, non-proprietary interoperable software.
- Reasonable private copying rights for consumers, researchers, students and educators should be ensured.

Finally, the agreement should respect countries' national sovereignty and right to retain flexibility in creating limitations and exceptions consistent with their national policies and their existing international obligations.

## Session Six

### ***Rules and Systemic Issues: Non-Violation – Dispute Settlement Issues in IPRs, and Technology Transfer***

Non-violation complaints were incorporated into the multilateral trading system for the purpose of ensuring tariff concessions and are thus questioned in the current international trade framework. Their applicability to intellectual property is particularly challenged as non-violation complaints do

not respond to the *sui generis* nature of, for instance, the TRIPS Agreement. Moreover, intellectual property only serves as an instrument of public policy if its inherent balance between public and private interests is respected and countries have the flexibility to design their particular regimes to match their circumstances and needs. Non-complaints would further tip the balance in favour of the producers of intellectual property and constrain domestic regulatory measures. As a result, Article 2 of the Chapter on Dispute Settlement of the FTAA should limit the scope of non-violation complaints to exclude the IP chapter.