



**Symposium on Public Health, Intellectual Property
and TRIPS at 20: Innovation and Access to
Medicines: Learning from the Past, Illuminating the
Future-2015**

**National experience in negotiating and
implementing trade agreements
October 28, 2015**

EXPERIENCE IN FTA NEGOTIATIONS

SINCE 2003: 19 FTAs

- PERU-US
- PERU-UE
- PERU –EFTA
- PERU-JAPON
- PERU-CANADA
- PERU-SINGAPUR
- PERU-CHINA
- PERU-TPP

EXPERIENCE IN FTA NEGOTIATIONS

PERU-US FTA

Intellectual Property

- “May 10” Agreement established a framework for the U.S. trade policy, allowing developing countries to abide by more lenient IP standards on a permanent basis.
- Pharmaceutical Clinical Data Protection: access window, normally 5 years for new chemical entities, considerable efforts, abbreviated procedures of bioequivalence.

EXPERIENCE IN FTA NEGOTIATIONS

PERU-US FTA

Pharmaceutical patents:

Compensation for delay is optional.

Soft linkage is optional vs. Transparency System.

EXPERIENCE IN FTA NEGOTIATIONS PERU-EU FTA

Intellectual Property

- **Resolution WHA 61.21.**
- **Pharmaceutical clinical data protection**
FN: undisclosed information protection
for biologicals in accordance with TRIPS
art. 39.2, access window, normally 5
years for new chemical entities.

PATENTS: best efforts for compensation.

EXPERIENCE IN FTA NEGOTIATIONS PERU-EFTA FTA

Intellectual Property

- **Pharmaceutical clinical data protection: new chemical entities, access window, normally 5 years, abbreviated procedures of bioequivalence.**
- **Pharmaceutical patents: best efforts to avoiding delays in Patent Offices. Possibility to extend it in case of delays in marketing approval.**

EXPERIENCE IN FTA NEGOTIATIONS PERU-CHINA FTA

Intellectual Property

- **Recognizing the Doha & Public Health Declaration, the Decision of August 30, 2003 on Par. 6 implementation.**

Cooperation and capacity building

TBT

Cooperation

EXPERIENCE IN FTA NEGOTIATIONS

PERU-JAPON FTA

Intellectual Property

- Idem TRIPS

TBT

Cooperation

EXPERIENCE IN FTA NEGOTIATIONS

PERU-SINGAPUR FTA

Intellectual Property

- No Chapter

TBT

EXPERIENCE IN FTA NEGOTIATIONS PERU-CANADA FTA

Intellectual Property

- **No patents.**
- **No protection of undisclosed test data.**

TBT

EXPERIENCE IN FTA NEGOTIATIONS PERU-PACIFIC ALLIANCE FTA

Intellectual Property

- **No chapter on IP.**

TBT: Annex for cosmetic technical regulation.

EXPERIENCE IN TPP FTA NEGOTIATIONS

INTELLECTUAL PROPERTY RIGHTS

- Linkage
- Compensation for delays in the patent office and during marketing approval
- New protection for chemical entities in combination.
- New protection for new clinical information
- New effective market protection for biologics: proteins
- Other measures that contribute to the effective market protection
- Removal of “considerable efforts”
- “Undisclosed test data” vs. “information”

EXPERIENCE IN TPP FTA NEGOTIATIONS

TECHNICAL BARRIERS TO TRADE

Harmonization of:

- pharmaceuticals
- medical devices
- cosmetics
- alcoholic beverages
- labeling of foods regulations

EXPERIENCE IN TPP FTA NEGOTIATIONS

- **INVESTMENT:**

Non-discriminatory measures to protect public interest do not constitute indirect expropriation.

No obligation to pay compensation for any unfavorable economic impact that such measures have on an investment.

- **REGULATORY COHERENCE:**

Provide precise and specific instructions on the development of technical regulations by central government.

Institute a central body to supervise/coordinate the decision-making process of government agencies and review regulatory measures.

Implement the conduct of Regulatory Impact Assessments (RIA) by the central body in the development of technical regulations.

EXPERIENCE IN TPP FTA NEGOTIATIONS

- **REIMBURSEMENT**

Requirements regarding the process for listing the pharmaceutical products and medical devices for reimbursement purposes and prices determination made by health authorities used in health care programs.

Pharmaceutical companies can appeal during the decision-making process of the health authority.

- **SANITARY AND PHYTOSANITARY MEASURES**

Provides consultative and State-to-State dispute settlement mechanisms to resolve SPS issues, where shipments of food or agricultural products are held at the border due to an SPS problem.

EXPERIENCE IN TPP FTA NEGOTIATIONS

- **TOBACCO EXCEPTION**

There is concern about the Investor - State Dispute Settlement to be extended to the TPP countries, which would allow the situation that occurred with Philip Morris suing the Australian government over plain packaging law.

EXPERIENCE IN FTA PERU-US & IMPLEMENTATION

- **PATENTS AND DATA PROTECTION**
 - **LAWS**
 - **REGULATIONS**

EXPERIENCE IN FTA PERU-US & IMPLEMENTATION

DATA PROTECTION LAW AND REGULATION

- **Definition of New chemical entity**
- **Undisclosed test or other data on safety and efficacy**
- **Conditions and the protection period**
- **Abbreviated procedure of bioequivalence**
- **Exceptions and limitations**
- **Transparency**
- **Opposition procedures**
- **Generation of information (as Bolar Exception for patents)**

EXPERIENCE IN FTA PERU-US IMPLEMENTATION

PATENT LAW

- Adjustment for unreasonable delay. Exception for pharmaceutical patent
- Bolar Exception (for experimental use and early working)
- Conditions for compulsory licenses
- Penalty for reckless opposition (\$ 60,000)

EXPERIENCE IN FTA PERU-US FTA & CERTIFICATION

Certification process was monitored closely by the USTR by means of electronic media, teleconferences and in-person meetings during the year.

EXPERIENCE IN FTA PERU-US FTA & ADMINISTRATION

- Once a year officials from the Peruvian Patent office and the Health Ministry hold meetings with the USTR officials to report on the enforcement of the FTA with regard to patents and the protection of clinical data.
- Statistical information on patents granted and protected clinical data is reviewed.
- To-date no issues occurred with regard to the legal implementation of this FTA provisions and the administration of the clinical data protection and patented pharmaceuticals.

EXPERIENCE IN FTAs: Lessons Learned

In case of Peru :

- **Consistency of the FTA Peru-US standard in all FTAs preceding the TPP.**
- **Peru struck an almost perfect balance between intellectual property rights and access to medicines (atazanavir compulsory license).**
- **Departure from the so-called “May 10” Agreement which established a framework for the U.S. trade policy, allowing developing countries to abide by more lenient IP standards on a permanent basis.**

EXPERIENCE IN FTAs: Lessons Learned

In case of developing countries :

- Next generation trade agreements overriding WTO standards: new concepts of protection, new subject-matter to be protected.
- Importance of the involvement of health officials at the start of the FTA negotiations on chapters which may affect access to medicines, their careful preparation on trade agreements` issues which may affect access to medicines and their ability to assess the change in their own regulations taking into account the degree of economic development of their countries.
- Keeping close to officials from the Trade sector in their countries and trying to convince them for the potential effect on the health of the population be taken into account in negotiating the FTAs.

EXPERIENCE IN FTAs: Lessons Learned

In case of WTO :

- Next generation trade agreements overriding WTO standards: new concepts of protection, new subject-matter to be protected.
- Trade agreements now go straight to the heart of the regulations like the new Regulatory Coherence Chapter in the TPP and the Pacific Alliance.
- New matters being regulated: TBT annexes on pharmaceuticals, medical devices, cosmetics, alcoholic beverages, labeling of foods regulations.
- New worldwide standard?

