Negotiating IP provisions in trade agreements: Latin America experience

Local Pharmaceutical Production and the Trans-Pacific Partnership Negotiations: Intellectual Property Provisions

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Outline

1. Introductory observations
2. Free trade agreements and intellectual property with particular reference to the Latin American experience
3. The TPPA
4. Lessons, concluding observations

The FTAs and the international intellectual property (IP) architecture

- Free trade agreements (FTAs) adopt different names but essentially deal with variety of trade issues (liberalization of trade, services, procurement, trade facilitation). They also include new issues such as FDI and IP chapters
  - The single undertaking concept
- FTAs deepen the minimum standards of protection and enforcement under TRIPS
  - TRIPS-Plus/extra provisions?

TRIPS and FTAs

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

Article 1 (the minimum standards), TRIPS

USA and the expansion of the trade agenda

- Main supporter of agreements seeking stronger and robust IP international commitments
  - Domestic agenda: US trade laws (e.g., Section 301)
  - Multilateral agenda: Role played in TRIPS
  - Regional agenda: Free Trade Agreement of the Americas (FTAA)
  - Bilateral Agenda: FTAs
  - Plurilateral initiatives: Asia- Pacific Economic Cooperation (APEC), ACTA, TPPA,
- US agreements main focus of presentation

Main FTAs negotiated by the USA

1985-1990s	2000-2004	2005-2009	2010s
-Israel -NAFTA: Canada and Mexico	-Vietnam (Bilateral Trade Agreement) Jordan -Chile -Singapore -Australia -CAFTA- DR: Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua and Dominican Republic	-Bahrain -Morocco -Peru -Colombia -Panama -Oman	-KORUS

Principal objective in IP negotiations

"The principal negotiating objectives of the USA regarding trade-related intellectual property are…
-ensuring that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the USA reflect a standard of protection similar to that found in US law…"

The Trade Promotion Authority (Trade Act of 2002), Section 2102

EU trade agreements

Association Agreements, and Stabilization and Association Agreements	Economic Partnerships Agreements	Partnership and Cooperation Agreements and Association Agreements	Association Agreements and Trade Agreements
With candidates and potential candidates for accession	Focus on African, Caribbean and Pacific States CARIFORUM	European Neighbourhood Policy, Euro Mediterranean agreements	Chile Mexico South Africa Colombia, Peru Central American countries [In June 2012 the EU and Vietnam launched negotiations for a comprehensive free trade agreement with a view to ensuring an effective environment for trade and investment relations.]

Features of EU trade agreements

- First generation of EU agreements sought mainly enforcement and implementation of TRIPS and commitment to “observe high international standards” and adhere to treaties pertaining to the international IP architecture
- Recent second generation of agreements (CARIFORUM, Peru, Colombia) are more ambitious stressing issues such as
  - Pharmaceutical products
  - Geographical indications
  - Enforcement

Other actors

- EFTA has negotiated agreements including IP chapters with
  - Chile, Colombia, Croatia, Egypt, Golf Cooperation Council, Israel, Jordan, Lebanon, Macedonia, Mexico, Morocco, Palestinian Authority, Serbia, Singapore, SACU, Rep. of Korea, Tunisia , Turkey
- Japan has concluded EPAs with
  - Mexico, Chile, Malaysia, Thailand, Indonesia, Brunei, Philippines, Vietnam, India, Peru
- China has concluded FTAS with
  - Pakistan, Chile, NZ, Singapore, Peru, Costa Rica, Switzerland

The sensitivity of IP-health related issues

- The treatment of pharmaceutical products and processes has been a sensitive area in the evolution of IP
- Historically, was a subject area -at least with respect to products- excluded from patentability
- Before TRIPS, under the 1883 Paris Convention, countries were free to determine the scope and extension of protection
  - By 1987 (study by WIPO) close to 50% of laws excluded the protection of pharmaceutical products

IP-health related issues post-TRIPS

- With TRIPS no technological field could be discriminated from patent protection, thus pharmaceutical products and process benefit from same treatment as all other fields
  - This status has been reinforced by post TRIPS developments such as FTAs and related arrangements
    - -Note Bilateral Agreement of 2000, Vietnam and USA (Art. 7)

2. Free trade agreements and intellectual property with particular reference to the Latin American experience

General features of FTAs: follow general structure of TRIPS but differ in style and intensity of obligations

1. Link with the international IP architecture and agreements parties need to be obliged to
2. National treatment and MFN are principal components
3. Minimum standards of protection and enforcement
4. Parties might adopt measures necessary to prevent anticompetitive practices that may result from the abuse of the intellectual property rights

General features of FTAs: Agreements follow general structure of TRIPS but differ in style

5. Gives rise to obligations in respect of all subject matter existing at the date of entry and no obligations with respect to pre existent acts
6. Transparency with respect to all laws, regulations, and procedures concerning the protection or enforcement of IPRs that shall be in writing and be published
7. Broad coverage of IP disciplines (see next)

Overview: contents of FTAs of latest generation: USA-Peru

1. General provisions
2. Trademarks
3. Geographical indications
4. Domain names on the Internet
5. Copyrights
6. Related rights
7. Obligations common to Copyright and related rights
8. Protection of Encrypted Program-Carrying Satellite Signals
9. Patents
10. Measures related to certain regulated products
11. Enforcement of IPRs
12. Promotion of Innovation and technological development
13. Understandings Regarding Certain Public Health Measures
14. Final provisions

Patents and regulated products

On patents the scope of provisions in FTAs builds on TRIPS but go beyond in some respects. The provisions deal in general with

1. Patentability criteria
2. Plants and animals
3. Exceptions
4. Nullification and revocation
5. Duration and cases of restoration

Patentability of plants and animals

- Criteria is not uniform
  a. Prevalent criteria: Parties to undertake all reasonable efforts to make patent protection available and any Party that provides patent protection for plants or animals on or after the date of entry into force of the FTA shall maintain such protection (Latin American FTAs)
  b. Patents should be available for plants and animals. In addition, patents shall be available for any new uses or methods of using a known product, including new uses of known product for the treatment of human and animals (Morocco)

Patent exceptions and limitations

- FTAs make provisions for limited exceptions to the exclusive rights conferred by a patent, in line with Art. 30, TRIPS, and in general provide for a regulatory exception (Bolar)
- On compulsory licenses –excepted earlier US FTAs (Jordan)- agreements do not alter principles of TRIPS and do make reference to 2001 Doha Health Declaration

Duration and restoration: FTAs innovate with respect to TRIPS in two respects

1. Compensations for unreasonable delays in the issuance of a patent by restoring the patent term or patent rights. It is normally considered unreasonable a delay –not attributable to patentee- in the issuance of the patent of more than five years from the date of filing or three years after a request for examination
2. Compensation for unreasonable curtailment of the effective patent term resulting from the marketing approval process

Regulated products: 3 main innovations with respect to TRIPS

1. Exclusive protection with respect to third parties for 5 years (pharmaceuticals)- 10 years (agro-chemicals)- for undisclosed data on safety and efficacy of products submitted for the commercialization or sanitary approval of products
2. The commercialization of a generic product is not allowed while a patent is still in force without the consent or acquiescence of the right holder. The latter should also be notified of the identity of the generic firms requesting permits. The so called “linkage”

Regulated products: 3 main …

3. Some agreements provide that with respect to data that was previously submitted to obtain marketing approval in the territory of other Party, firms may enjoy same protection of 5-10 years by seeking protection in the territory of the Party within 5 years after obtaining marketing approval in the other territory

The May 2007 US bipartisan agreement related to health

1. As a result, FTAs under negotiations with Peru, Colombia and Panama made optional and not mandatory provisions related to compensations for delays and “linkage”
2. At the same time, the protection of undisclosed test or other data should not exceed “a reasonable period of time”, such a timeframe shall normally mean five years, taking into account the nature of the data and the degree of effort and expenditure required to produce the data

The May 2007 US bipartisan …

3. The FTAs revised by Congress, departing from the earlier ones, call on Parties to reaffirm their commitments to the Doha Declaration, particularly emphasising that the provisions on data exclusivity should be subordinated to the right of a Party to take measures to protect public health

FTAs are more specific and prescriptive on enforcement issues

1. Relative "flexibility" for implementation
   - No obligation to put in place a judicial system for the enforcement of IPRs distinct from that for the enforcement of law in general nor with respect to the distribution of resources for enforcement of IPRs and the enforcement of law in general. But, a decision that a Party makes on the distribution of enforcement resources shall not be a reason for non-compliance
2. Judicial authorities shall have the authority to order the infringer to pay damages adequate to compensate for the injury the right holder has suffered as a result of the infringement

FTAs are more specific and prescriptive …

3. In civil judicial proceedings -at least with respect to infringement concerning copyright or related rights and trademark counterfeiting- need to establish or maintain pre-established damages, which shall be available on the election of the right holder as an alternative to actual damages.
4. With respect to provisional measures parties shall act on requests for relief in *audita altera parte* and execute such requests expeditiously according to its rules of judicial procedure.

FTAs are more specific and prescriptive …

5. Competent authorities may initiate border measures *ex officio* with respect to merchandise for importation, exportation, or in transit
6. Expansion of measures related to criminal procedures and measures

Summing up: the controversial health-related questions in FTAs

	Chile-USA	CAFTA-USA	Peru-USA	KORUS
Supplementary extensions for delays			Optional for pharmaceuticals	
Data exclusivity protection				
Linkage			Optional	
Plant protection				
Stricter enforcement measures				

One important lesson: signing an agreement is not the end of the story

- More critical is the implementation process and the human and institutional capacities to do it well
- Signature and ratification is followed by different distinctive phases:
  i. Domestic adaptation to the new obligations
  ii. Allowance to counterpart to have a say in legislative changes to meet expectations of FTA
  iii. Formal entry into force of the agreement
  iv. Close monitoring of compliance

i. Domestic adaptation to the new obligations

Experience differ in modalities of implementation

- Countries that negotiated FTAs in an earlier phase (Mexico, Chile) appeared to have enjoyed more room for implementation
- A the same time some countries have taken the challenge of modernizing their legislation and institutional base
  - Chile, for example, included a better articulation of compulsory licensing and modernized the institutions dealing industrial property. More attention is made to competition policies

Case of Peru and its implementation challenges

- 2006: initial signature of FTA
- 2007: US bipartisan agreement requiring adaption of initial agreement
- 2008: Legislative implementation through a number of legislative acts (institutional adjustments to INDECOPI, data protection statute, amendments to Andean Community regulations)
- 2009 (14 and 17 January): amendments to the 2008 legislative acts among others on data exclusivity (minimum protection of 5 years)
- 1 Feb. 2009: FTA entered into force

How Chile and Peru implemented data protection to safeguard public health concerns

Protection will not be granted or continue in cases of:

a) Anticompetitive behavior
b) Public health, national security, non-commercial public use, national emergency
c) Compulsory license
d) Product has not been commercialized in Chile within 12 months from the date of registry or sanitary approval in the country
e) The product has a registry or authorization in a foreign country or more than 12 months

ii. Opportunity to counterpart to have a say on domestic legislative changes to meet expectations of the agreement

- Under US law, parties to FTAs are under the obligation to take measures to adjust their internal IP regimes to the new FTA standards, prior to the entry into force of the Agreement
  - Industrial groups do urge the government not only to monitor very closely the implementation by Parties of their FTA obligations but also “to ensure that they have in place, before the entry into force of the FTAs, national legislation that faithfully reflects their FTAs obligations”

Peculiarities of US trade law

- FTAs are non considered self-executing and explicitly do not alter domestic legislation
  - The USTR has expressly advised Congress -in the ratification process of FTAs- that it may adopt subsequent legislation inconsistent with the terms of an FTA
    - It has also advised Congress that decisions of dispute settlement panels under the FTAs do not affect US Federal law unless those decisions are expressly given effect by Congress.
  - This understanding has been reiterated in the recent case of ACTA

iii. Entry into force and iv. Close monitoring of compliance

- Once agreements enter into force they are closely monitored in terms of compliance
- For example: USTR characterization of countries with respect to their IP performance and its annual reviews (Section 301 reports)
- FTAs partners risk more exposure to these unilateral monitoring processes

USTR: Main observations regularly made to implementation of FTAs in Latin America

- Progress made is acknowledged but not considered enough
- Major concern relates to insufficient protection of pharmaceutical products and disagreements regarding the adequate protection of undisclosed data
- Dissatisfaction with form and attitude by public authorities to fight piracy and counterfeiting and lack of resources nor priorities
- Great deficiencies noted on the fulfilment of obligations regarding the digital environment

Study on the impact of FTAs in five countries

Study and survey sponsored by the Inter-American Bank, 2010. We analyze through interviews with stakeholders the possible impact of IP provisions with respect to

- Rule of law
- Institutional base
- Transparency and role of civil society
- Business climate
- Dialogue with private sector
- Factors influencing implementation

Lessons drawn from negotiations and implementation experience

1. Implementation to be seen in broader context of challenge for State modernization
2. Need for local capacities to negotiate, understand nature of commitments made (e.g., international treaties to adhere), and implications of US law transplanted into FTAs
3. Transparency in negotiations and implementation involving different segments of society: identification of national needs/interests

Lessons drawn …

4. A negotiating agenda. Generally on IP, a reactive and defensive agenda prevails
5. Negotiations do not end with the signature (case of certification)
6. Coherence with respect to positions taken multilaterally in other negotiating processes (CBD, WTO, WIPO)
7. Adequate human and institutional resources to assume challenges of implementation and exploring potential benefits

Lessons drawn …

8. Cost of implementation. This could be significant. There is no clear methodology on how to calculate costs
   - Which are the costs involved in negotiations proper and in the implementation phase?
9. An implementation plan to assume an efficient and balanced implementation

3. The TPPA

The IP health related questions in FTAs: a summary

Patent related questions	Regulated products	Enforcement issues
Patentability criteria	Protection of undisclosed information of products using a new chemical entity	FTAs deepen TRIPS provisions that could have consequences to access of medicines
Patentable subject matter: all fields of technology (pharmaceuticals)	Exclusivity for at least 5 years	TRIPS is stricter on questions of piracy and counterfeiting. It does not oblige countries to interventions by custom authorities regarding suspension of free circulation infringing goods in the case of patents
Exceptions (case of regulatory exception, Bolar)	Protection and exclusivity for 5 years of undisclosed information based on evidence of earlier commercialization in the other Party	FTAs include intervention of custom authorities beyond what is stipulated in TRIPS
Duration of patents and restoration (earlier and latest generation of FTAs)	The linkage: mandatory/ optional	Expansion of criminal sanctions
Compulsory licensing		
Doha Declaration		

Polarized views: Leaders' vision

"TPP countries have agreed to reinforce and develop existing World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) rights and obligations to ensure an effective and balanced approach to intellectual property rights among the TPP countries. Proposals are under discussion on many forms of intellectual property, including trademarks, geographical indications, copyright and related rights, patents, trade secrets, data required for the approval of certain regulated products, as well as intellectual property enforcement and genetic resources and traditional knowledge. TPP countries have agreed to reflect in the text a shared commitment to the Doha Declaration on TRIPS and Public Health."

http://www.ustr.gov/about-us/press-office/fact-sheets/2011/november/outlines-trans-pacific-partnership-agreement

MSF perception

"The TPP negotiations are being conducted in secret, but leaked texts indicate that the U.S. government is demanding the most aggressive package of intellectual property (IP) protections ever seen in a trade agreement with developing countries. These provisions go well beyond internationally agreed upon standards for IP protection, and threaten access to affordable, generic medicines. The stringent IP provisions proposed in the TPP will keep the prices of newer medicines high and out of reach for Vietnam's patients, donors and government.

Vietnam has one of the fastest growing pharmaceutical markets in Asia, with annual growth rates at more than 13% every year between 2008 and 2011. By 2014, patented drugs will take up 21.55% of the total drug value. Approximately 50% of drugs have to be imported, and 90% of domestic pharmaceutical production relies on imported raw materials."

MSF, 2013

Asymmetries between TPP members

- TPP membership suggests important asymmetries in terms of:
  - Population
  - GDP
  - Terms of trade among members
  - R&D expenditures
  - Volume of IP related transactions
    - Number of patent applications and percentage between resident and non-resident applicants
    - Ratio of patents granted by number of inhabitants
    - Trademark applications

Patent applications in selected TPP countries: residents out of totals (%)

	2000	2005	2010
Australia	8.8	10.7	9.7
Chile	7.7	12	30.5
Malaysia	3.3	8.3	19.1
New Zealand	20.8	27.0	23.9
Peru	3.7	2.6	13.0
Singapore	6.3	6.6	9.2
Vietnam	5.2	16.5	8.5
USA	55.7	53.2	49.4

The leaked proposals and their health related implications

- Negotiators face challenges in grasping full picture of scope of proposals
- It is not only a matter of patent related provisions
- Proposals are disperse but in the main they encompass:
  - USTR so called Trade Enhancing Access to Medicines (TEAM) announced at the 8th Round (September 2011)
  - Relevant patent provisions
  - Regulatory products provisions
  - TBT Annex
  - Transparency, reimbursements

Overview of main proposals and features

1. Precisions on patentability criteria and expansion of patentable subject matter (plants, animals, chirurgical and therapeutic methods)
2. Circumscription of exceptions and revocation grounds
3. Duration of patents
4. Administrative issues: pre-grant oppositions and modifications to applications and patent claims
5. Data protection to second uses and linkage
6. Minimization of regulatory barriers and trend to harmonize regulatory frameworks including guidance on reimbursement schemes

TEAM

- At Round 8 of the TPP negotiations (Chicago, IL), the Office of the USTR issued a white paper outlining a new strategic initiative entitled “Trade Enhancing Access to Medicines (TEAM).”
  - “TEAM is designed to deploy the tools of trade policy to promote trade and reduce obstacles to access to both innovative and generic medicines, while supporting the innovation that is vital to developing new medicines and achieving other medical breakthroughs”

TEAM

The white paper describes the following goals to be achieved by TEAM:

- Expedite access to innovative and generic medicines through a "TPP access window"
- Enhance legal certainty for manufacturers of generic medicines
- Eliminate tariffs on medicines
- Reduce customs obstacles to medicines
- Curb trade in counterfeit medicines
- Reduce internal barriers to distribution of medicines
- Promote transparency and procedural fairness
- Minimize unnecessary regulatory barriers
- Reaffirm TPP Parties' commitment to the Doha Declaration on TRIPS and Public Health

Main controversial issues around patent protection

a. Availability of protection for any new form, use or method of using a known product (8.1)
b. Patentability of plants and animals (8.2)
c. Patentability of diagnostic, therapeutic and surgical methods (8.2)
d. Adjustment of term of a patent to compensate unreasonable delays in the grant. A delay for more of 4 years from date of filing or 2 years after request for examination is considered unreasonable (8.6)
e. Pre- grant oppositions (8.8)

Controversial matters related to regulated products

a. Data exclusivity for at least five years on information concerning safety or efficacy for marketing approval (9.2 a, b)
b. Protection for at least 3 years of new clinical information essential to the approval of product containing the previously approved chemical entity including information for a product that was previously approved in another territory (9.2 c, d)
c. Special case of prior marketing approval by regulatory authority in another territory (9.4)
d. Provisions regarding transparent and effective measures in cases of marketing approval of products under patents(“linkage”) (9.5)
e. Special case: biologics (under consideration, 9.9)

Technical barriers to trade: Annex IV, pharmaceutical products

1. Trend to standardize regulatory procedures particularly those on approval of new products based on international developed guidance
2. Central and unique authority to regulate all aspects related to safety, effectiveness and manufacturing quality and to grant marketing authorization for pharmaceutical products
3. The determination to grant marketing authorization of commercialization of medical product should be made solely on the basis of information related to safety, efficacy, labelling and manufacturing quality of product
4. Establishment of procedures that are timely, reasonable, objective, transparent and impartial, without conflict of interest, including, an appeal process

Annex on Transparency and procedural fairness for healthcare technologies

Parties need to maintain procedures for listing pharmaceutical products or medical devices or indications for reimbursement, or for setting amount of reimbursement, including:

a. Consideration of applications to be made within a reasonable, specified time
b. Make transparent procedures and criteria used in the decision making process
c. Provide opportunities for applicants to give comments in the decision making process

Annex on Transparency …

d. Ensure that determination of amount for reimbursements is based on transparent and verifiable basis consisting of competitive market-derived prices, or an alternative transparent and verifiable basis consisting of other benchmarks that recognize value of patented or generic products
e. Provide detailed written information regarding basis for recommendations
f. Make available opportunities for independent appeal or review of recommendations
g. Publicize membership list of committees related to pricing and reimbursement

4. Lessons, concluding observations

Salient features of health related proposals

- FTAs has meant the “importation” of sophisticated pieces of legislation of more advanced countries
- But, exporting legal regimes in different contexts, traditions and based on contrasting regulatory regimes constitute a major challenge for importing country
- Proposals in the case of the TPPA are extremely detailed in nature, invasive in nature, transposing different legal traditions that demand experienced staff with great understanding of that legal tradition

Salient features …

- The “exporting” countries are endowed with resources, institutions and a system that provides “checks and balances”
  - Solid institutional base
  - Human resources to manage sophisticated regulatory and legal system including academic in the field with high reputation
  - Independent and experienced adjudicatory bodies
  - A legal profession used to manage complex situations
  - Competition authorities in place to balance excesses of the system

Incremental nature of IP provisions in FTAs and TPPA

- From the Paris Convention to TRIPS: the case of pharmaceuticals
- FTAs and the nature of the TRIPS Plus agenda
- ACTA: a plurilateral agreement to fill gaps in TRIPS and strengthen the enforcement of IPRs
  - The experiment and its vicissitudes
- The TPPA as the trade agreement of latest generation: a gold standard

Evaluation of impact could not be limited solely to IP issues

- Trade agreements cover a variety of trade issues. IP is one aspect among many. IP issues, however, could not be negotiated as traditional trade matters (e.g., tariff). They are of different nature
- IP chapters in trade agreements have been controversial components
  - They represent the confrontation between maximalist and minimalist views on IP protection
- Each country should reach its own decisions on the impact, benefits and costs of such arrangements where national interests should prevail

Negotiating an agreement is not enough…

"Vietnam remains on the Watch List in 2013. Although Vietnam took certain steps to improve its regulatory framework in the last two years … took further steps on public awareness efforts, enforcement actions have showed little progress in 2012…

Vietnam should clarify its system for protecting against the unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products…

The United States looks forward to continuing to work with Vietnam to address these and other issues, including in the TPP negotiations."

2013 Special 301 Report
http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf

Is your country prepared for trade agreements including ambitious IP provisions?

- Does the country has an appropriate regulatory system to assume respective new obligations and responsibilities explicit and implicit in trade agreement?
- Is there an institutional base to act accordingly and responsibly towards its own community and its foreign partners?
- Does the country has in place the checks and balances that do exist in more advanced countries?
- Does the country has a system that balances the interests of the research based industry and those of the generic competitors?
- Are instruments in place to control anticompetitive behavior?

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