



US - Latin-American FTAs & Access to Medicines: An Analysis of the Process

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Presentation Outline

1. Socioeconomic and political context of Free Trade Agreements (FTAs)
2. The process: US Principles and strategies of negotiation
3. The negotiation process in Colombia



• Inverse Health Law

• Institutions

- World Bank, International Monetary Fund, World Trade Organization
- Office of the United States Trade Representative...

• Policies

• FREE MARKET ECONOMIC POLICIES

1. Structural Adjustment Programs (SAPs)
2. Free Trade Agreements (FTAs)

• FREE MARKET HEALTH POLICIES

1. Market based Healthcare reform
 - Privatization & Decentralization
2. Intellectual property rights -TRIPs
 - Pharmaceutical patents

• SOCIOECONOMIC IMPACT

- Food insecurity
- Environmental deterioration
- Unemployment / Poverty
- Social polarization / Stress
- Migration...

• IMPACT ON HEALTH SYSTEMS

- Dismantling of disease control programs
- Private insurance
- Closing of public hospitals
- Expensive medications
- Commoditization of medicine...

• Impact

• IMPACT ON POPULATION AND INDIVIDUAL HEALTH :

- Poor quality of life, high morbidity/mortality, dramatic increase in risk behaviors
- Limited access to healthcare services and medicines

• Health Inequity within and among countries

• (Useche, LaRue, 2007)

“Competitive Liberalization” Or “Unleashing the Trade Winds”



•After Seattle 1999
Robert Zoellick, 2002

•“America has stated its intentions plainly. We will promote free trade globally, regionally and bilaterally...”

•“We will not passively accept a veto over America's drive to open markets.”.

•“America's *trade* policies are connected to our broader economic, political, and security aims”.

•Zoellick, Robert, “Unleashing the trade winds,” The Economist, London: The Economist Newspaper Ltd., 5 December 2002 [online: web] URL:

http://www.economist.com/displayStory.cfm?Story_ID=1477509 ■

Free Trade is a Bipartisan issue

Signing NAFTA.

President Clinton. September 14, 1993

“There are some issues that transcend ideology. That is, the view is so uniform that it unites people in both parties. This means our country can pursue a bipartisan policy with continuity over the decades. That's how we won the Cold War. That's how we have promoted peace and reconciliation in the Middle East. And that's how the United States of America has promoted freer trade and bigger markets for our products and those of other nations.”

President Clinton

•THE WHITE HOUSE Office of the Press Secretary

Changes to already negotiated FTAs Peru, Panama, Colombia, Korea

- “On May 10, 2007, in a surprise press conference late in the day, Bush administration officials, Speaker Pelosi, House and Senate Democratic and GOP trade committee leaders and New Democrat Coalition members unveiled the outline of a “deal” to facilitate new “bipartisan cooperation on trade”.



2. The process:

US Principles and strategies of negotiation

Patents for Pharmaceutical Products: A Very Brief History

General Agreement on Tariffs and Trade, (GATT)
Tokyo Round: 1973-79
Third World Countries Successfully Opposed to Patents

1980: Ends of “anti-trust
over patent law” era

WTO Trade-Related aspects of Intellectual Property Rights (TRIPS)
Pharma won 20 years patent protection

(Christopher May & Susan K. Sell, 2006)

Harmonization of patent law

Global pharmaceutical market for US PhRMA



Harmonizing by the highest level of patent protection

- US Level of patent protection (LPP) is the start point.
- US uses its power to impose higher LPP in FTAs negotiated with “allied” countries.
- LPP in FTAs are used as a pressure tool for consolidating Phrma’s global monopoly.

Paragraph 4, Doha Declaration, 2001

“We 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”.

“Bilateral and regional trade agreements allow trading partners *to reach agreement beyond what has been agreed to multilaterally...*”

(Emphasis added).

Mickey Kantor -former U.S. Secretary of Commerce and U.S. Trade Representative- (2005, p.4 & p.5)

Nature and Role of the USTR – “Special 301” Report

- It is a 1994 neoliberal adaptation of the Trade Act of 1974.

- It is aimed to identify and monitor any country that protects its economy “*even if it is in compliance with its obligations under the TRIPS agreement*” (USTR, 2005 emphasis added).

- It is a instrument to pressure FTAs

“Special 301”
1974 Trade Act
Amended in 1994

2006
Priority Watch List:
13 countries

China; Russia; India
Venezuela; Brazil...

2006 Watch List:
34 countries

European Union

2006 “Section 306”
1 Country

Paraguay

US Free Trade Agreements

- **Delay approval of generic drugs.**
 - **Require patent extensions.**
 - **Link drug approval to patent status.**
 - **Restrict compulsory licensing.**
 - **Prohibit parallel importation.**
 - **Expand patent protections.**
-
- **REP. HENRY A. WAXMAN**
 - **TRADE AGREEMENTS AND ACCESS TO MEDICATIONS UNDER THE BUSH ADMINISTRATION**

“TRIPS PLUS” Provisions in Latin-American FTAS

	TRIPS – Doha D.	NAFTA	CAFTA	Chile	Perú	Colombia
Patent term extensions	<u>Shall</u> not end before 20 years.	Yes Minimum 20 years <u>“May”</u> extend	Yes unreasonable delays in granting patent or marketing approval	Yes unreasonable delays in granting patent or marketing approval	Yes *	Yes* US Congress introduced change: It is optional, no mandatory
Data exclusivity	NO “Unfair competition” “Undisclosed test or other data”	Yes	Yes	Yes	Yes *	Yes* US Congress introduced change: It is optional, no mandatory
Linkage	NO	NO	Yes	Yes	Yes *	Yes* US Congress changed: It is optional, no mandatory

Latin American FTAs

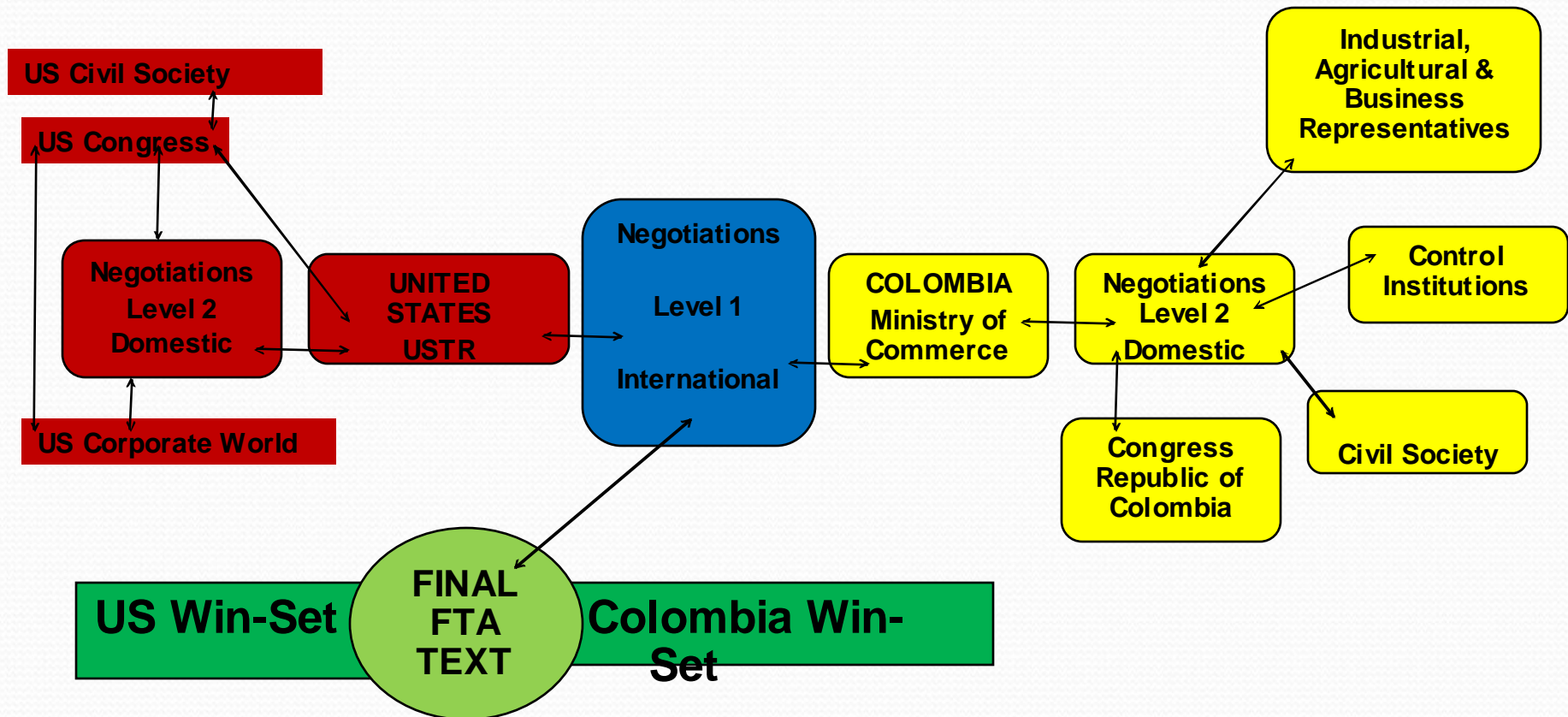




3. The process in Colombia

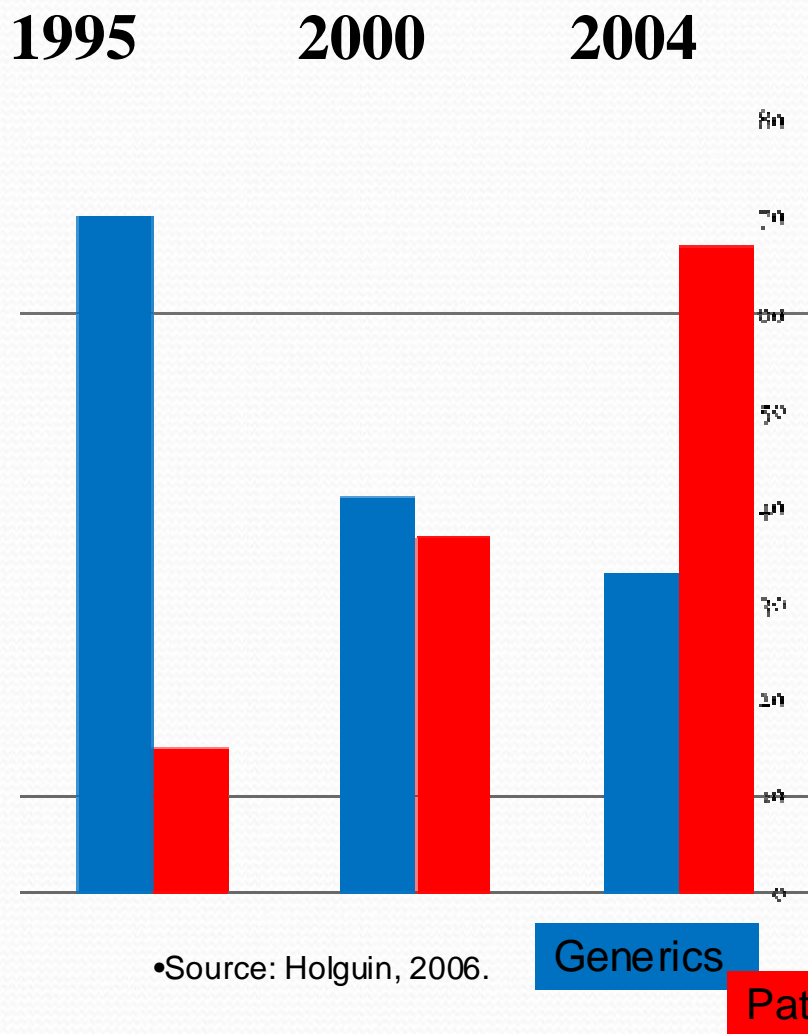
The Negotiation Process in Theory

Based on Robert Putnam's Model:
Diplomacy and Domestic Politics: The Logic of Two-Level Games"



Adapted from: Silva, L.C. (2007). **El proceso de negociación del TLC Colombia-Estados Unidos**. Colombia Internacional Nº. 65 pp. 112-133

Pharmaceutical Market in Colombia



US placed Colombia in the Priority Watch List of the Special 301 report



•Colombia issued Decree 2085 Conceding 5 years of data protection



•Congratulations for the: “exemplary progress ...on data protection”
& Colombia was promoted to the Watch list!

Generics' Competition

- “Generics produced by independent pharmaceutical companies are effective in reducing prices and improving population access to essential medicines.
- When a patent expires, prices drop between 22% and 80%.
- World average price of a generic is 1/3 of its bio-equivalent patented brand. In Colombia it is 1/4.
- Due to cheap prices and good quality, the generics industry supplies 67% of Colombian medicines.

Conclusion: “improving access to medicines requires increasing the supply of cheap and good quality generics”

German Holguín Zamorano Misión Salud

Colombian Industry of Generics Opposes the FTA

“Mission Health” & IFARMA

- Holguin, G. (2007). FTA: The truth.
- Cortes et al (2007). Impact of FTA in HIV/AIDS Patients
- Rossi, F. (2006). Did we save the Generics?
- WHO/PAHO/IFARMA (2005 FTA Impact on Access to Medicines...)

Impact of FTA

- It will increase health expenditures in US \$ 500 million by 2010 and \$900 million by 2020
- Prices of medicines will increase an average of 30%-40%
- Patented pharmaceuticals will have 60% of market (Currently only 4 %)

The Opposition to US - Colombia FTA

- 2003 - Creation of Colombian action network against FTA: RECALCA
- 2004 - Demonstration in Bogota
- 2005 - 52,000 indigenous people from the Cauca region voted in a referendum to reject the signing of a FTA with the US. 98% voted: NO
- During the negotiation period, Senator Jorge Robledo cited 9 political debates on the impact of the FTA

Bogota September, 2004



A negotiator resigns

“Restrepo expressed his complete disagreement with the proposals of the Office of the United States Representative because he thinks that they contribute to price increases of the medications which would affect low income populations”

La República. 4/12/2005

Economía

Ediciones Anteriores 4/12/2005

Reveladora carta de renuncia

CUESTIONA NEGOCIACIÓN DEL TLC • Luis Guillermo Restrepo, negociador colombiano del TLC, informa que su país presentó unilateralmente una propuesta que complicaría las negociaciones de Perú y Ecuador. • Resalta diferencias internas en las mesas de propiedad intelectual.

Marienella Ortiz.

Una carta pública fechada el viernes 2 de diciembre da cuenta de la renuncia de Luis Guillermo Restrepo Vélez, funcionario colombiano del sector Salud que acompañó las negociaciones del Tratado de Libre Comercio (TLC) con EEUU durante estos casi dos años de conversaciones.

En esta misiva, Restrepo da cuenta de su total rechazo al curso de las negociaciones frente a las propuestas de la Oficina del Representante de Comercio de EEUU, pues considera que contribuyen al incremento del precio de los medicamentos, lo que afectaría a las poblaciones de escasos recursos.



Luis Guillermo Restrepo.

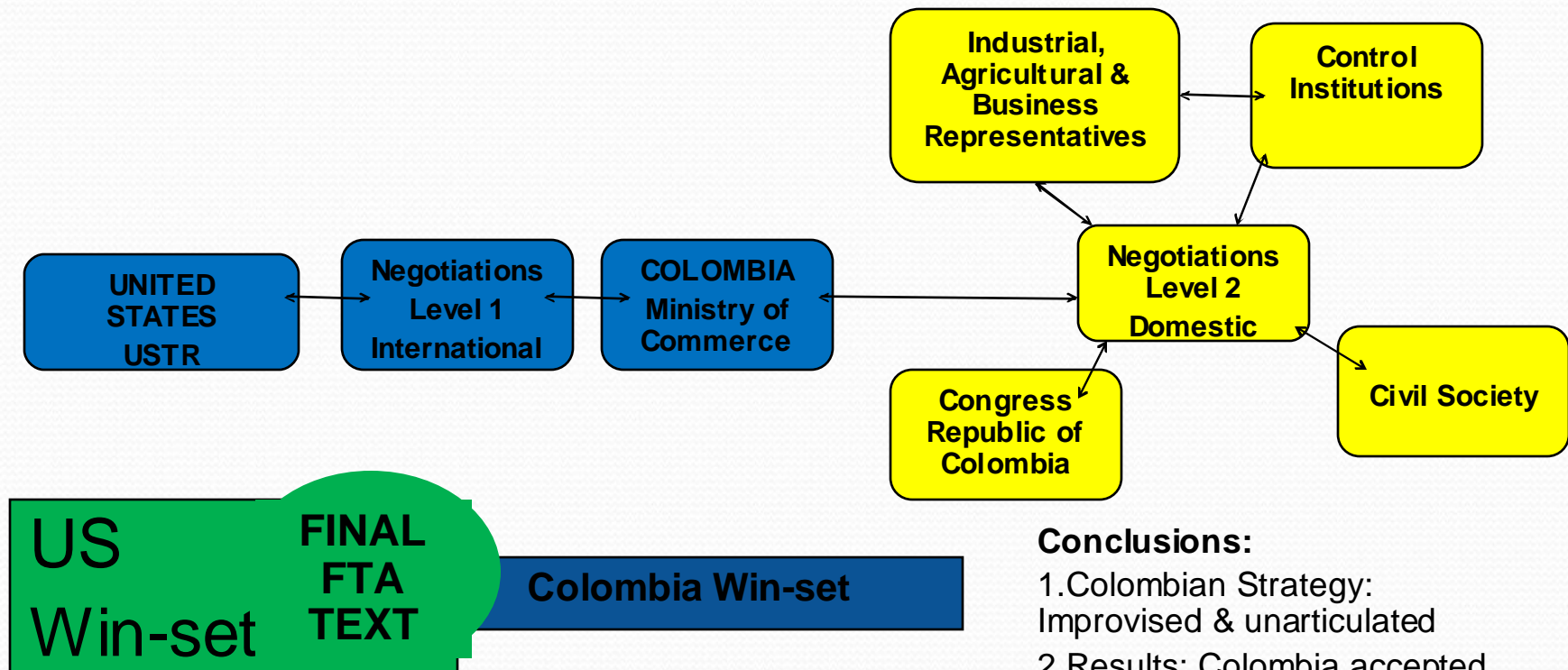
Para tener en cuenta

El negociador deploró la forma desleal en que los negociadores de comercio trataron al sector Salud.

Colombia's Negotiation Strategy

(Silva, 2007)

Based on Robert Putnam's Model:
Diplomacy and Domestic Politics: The Logic of Two-Level Games"



Conclusions:

1. Colombian Strategy: Improvised & unarticulated
2. Results: Colombia accepted the US proposal

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Big Pharma Pressures for More Concessions

- “Report of the Industry Trade Advisory Committee on Intellectual Property Rights [ITAC-15]”
 - Colombia must “provide effective legal means to enable a patent owner to prevent” parallel imports as was explicit in the FTA with Morocco
 - In Article 16.9.6 which establishes compensations for delays in the marketing approval process, the definition of “unreasonable delays” must be reduced to one year as was accepted by Peru
 - The obligation of granting patent protection “for all forms of new, non-obvious and useful inventions” must be explicit
 - In order to avoid “misinterpretations of the intellectual property obligations”, the final text not only of the FTA with Colombia but of all future FTAs should “track the FTA language contained in the U.S. model text
 - Etc...

