

Access to Medicines and Free Trade Agreements

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Why “Free” Trade?

Theory of Comparative Advantage

- ❖ Justification from the theory of “Comparative Advantage”, proposed by the 19th century economist, David Ricardo.
- ❖ Nations optimise productivity by specialising in areas where they have a comparative advantage.
- ❖ Translates into countries producing or manufacturing and then trading select commodities where they have an advantage.
- ❖ Lead to rise in global productivity and translate into greater well being for all.
- ❖ Countries encouraged **not** to build capabilities in areas where they do not have a “comparative advantage”

Free Trade – From Theory to Practice

- ❖ Assumes that those who have a “comparative advantage” will always maintain this advantage.
- ❖ Assumes that nations that are disadvantaged due to historical reasons will continue to remain disadvantaged.
- ❖ Maintains the presence balance between developed and developing nations.

Free Trade – Myth and Reality

- ❖ No nation has successfully industrialised under a regime of unrestricted trade.
- ❖ US in the 19th century, Japan in the 20th century, Korea and Taiwan in the late 20th century – examples of economic and technological development where domestic industries sheltered from foreign competition.
- ❖ In the post-war world, economic growth has contracted as free trade has expanded.
- ❖ In the 25 years of liberalised global commerce, compared with the period prior to 1973 when it was more regulated, productivity and growth rates of both industrialised and developing economies have come down.
- ❖ Economic growth does not translate into development -- especially growth through trade liberalisation, which favours a small elite and increases inequity

Freed Trade Agreements – A Paradox?

Article 24 (8b) of GATT:

*"A free-trade area shall be understood to mean a group of two or more customs territories in which the duties and **other restrictive regulations of commerce** (...) are eliminated on **substantially all the trade** between the constituent territories in products originating in such territories"*

- ❖ BUT the supposed cornerstone of the WTO is the Most-Favoured-Nation (MFN) treatment among the member-countries -- means that countries *cannot discriminate between their trading partners*
- ❖ FTAs sit on top of the multilateral system, creating "**more favoured**" trading partners
- ❖ Since Customs Unions predated GATT, an exception to the MFN treatment was made
- ❖ BUT most FTAs are about free trade areas, only about 5% about customs unions.

Why FTAs – Circumventing WTO

- ❖ Dispute Settlement Understanding (DSU) of the WTO offers weaker states opportunities to defend interests
- ❖ Every WTO Ministerial since 1999 (Seattle) has ended with developing countries obstructing proposals by US and EU
- ❖ Especially for the US, FTAs are a route to circumventing the logjam of WTO negotiations
- ❖ In a decade the WTO had received more notifications than had the GATT in the previous 46 years.
- ❖ FTAs negotiated since the WTO covering many of the same areas that are already the subject of obligations under WTO agreements.

FTAs involving the US – Forum Shifting

- ❖ In FTAs that the US has signed, dispute settlement chapters contain choice-of-forum provisions.
- ❖ Gives the complaining state (which is generally the stronger partner) choice of forum where there is breach of obligation under more than one trade agreement
- ❖ The capacity of a strong state to choose its legal battleground shifts the contest out of the multilateral setting of the WTO.

US has a history of using Bilaterals to impact on Multilateral Forums

- ❖ In 1980s US created conditions for the inclusion of an agreement on IP in the Uruguay Round through a series of bilateral negotiations on IP with countries like Brazil, Singapore and South Korea -- able to break the resistance of developing countries

Choice of Forum - US-Chile FTA

Article 22.3: Choice of Forum

- ❖ Where a dispute regarding any matter arises under this Agreement and under another free trade agreement to which both Parties are party or the WTO Agreement, the complaining Party may select the forum in which to settle the dispute
- ❖ Once the complaining Party has requested a panel under an agreement referred to in paragraph 1, the forum selected shall be used to the exclusion of the others.

Explicit Signalling of Intent

"The U S trade strategy, however, includes advances on multiple fronts. We have free trade agreements with six countries right now. And we're negotiating free trade agreements with 14 more. All our free trade agreement partners, some quietly, some more actively, tried to help over the course of the past couple of days. The results are very revealing to me, that over the past few days, a number of other developing countries, that are committed to opening markets and economic reforms, expressed their interest in negotiating free trade agreements with the United States".

US Trade representative Robert Zoellick said after the fiasco of the Cancun WTO meeting:

US led FTAs – IP issues with Impact on Access to Medicines

- ❖ Patentability
- ❖ Patent term
- ❖ Patent extensions
- ❖ Limitations on oppositions
- ❖ Protection of data
- ❖ Linkage of data protection, marketing approval and patent term
- ❖ Compulsory licences
- ❖ Parallel importation

Patentability

Allow for:

- ❖ Life Form (Micro-organisms, Plants and Animals) Patenting
- ❖ Patenting of “New” uses or methods of using a known product (*evergreening*)

Patent term extensions

Provide for extension of patent term to compensate patentee for:

- ❖ “Unreasonable” delays that occur in granting the patent
- ❖ The marketing approval process causing “unreasonable” curtailment of the effective patent term

Linkage of test data protection and marketing approval

Marketing approval body to prevent marketing during the patent term

- ❖ Has effect on use of compulsory licences and government use
- ❖ Has effect even if there is no patent protection

Compulsory licences

- ❖ Limited to Government and non-commercial use
- ❖ Limitations on grounds for compulsory licences

Parallel importation

- ❖ Parallel importation without the patentee's consent not allowed

US FTAs in Force

Israel - incl. Palestinian Authority: 1985

North American Free Trade Agreement -- Canada and Mexico: 1994

Jordan: 2001

Australia: 2004

Chile: 2004

Singapore: 2004

Bahrain: 2006

Morocco: 2006

Oman: 2006

Peru: 2007

Central America Free Trade Agreement - incl. Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic: 2008

Panama: 2008

Colombia: 2008

US- led FTAs under Negotiation

South Korea

Free Trade Area of the Americas -- incl. all countries on the Western Hemisphere

Middle East Free Trade Area -- incl. most countries in the "Middle East"

Transatlantic Free Trade Area -- European Union

Thailand

New Zealand

Ghana

Indonesia

Kenya

Kuwait

Malaysia

Mauritius

Mozambique

United Arab Emirates

US-Southern African Customs Union Free Trade Agreement -- incl. South Africa,

Botswana, Lesotho, Swaziland, and Namibia

Ecuador

Qatar

Impact of US-led FTAs

- ❖ According to the World Health Organisation's (WHO) economic model, the **full effect** of the stronger intellectual property (IP) protection required by the United States in all its FTAs will **not be felt for more than 15 years**.
- ❖ **Canadian estimates** show that if data exclusivity had been in force in Canada over the last five years, it would have cost an additional **\$600 million** for prescription medicines alone.

Impact of US-led FTAs – Case Study of Jordan

TRIPS-Plus Measures in the FTA

- ❖ Forbids parallel importation without patent holder's prior consent.
- ❖ Introduces five years of data exclusivity that commences on the medicine's date of registration in Jordan
- ❖ Patent linkage with marketing approval by regulatory authority
- ❖ Additional three years of data exclusivity (beyond five years) for new uses of already known chemical entities
- ❖ Compulsory licensing permitted only to remedy an anti-competitive practice, in case of public non-commercial use, or in the case of national emergency or other situations of extreme urgency.
- ❖ Patent extension for unreasonable curtailment of patent term as a result of a delay in the marketing approval process

Case Study of Jordan – contd..

Impact of the FTA on Access to Medicines (based on OXFAM's Study)

- ❖ Of medicines launched since 2001, 79 per cent have no competition from a generic equivalent
- ❖ By 2006 additional expenditures for medicines were between \$6.3m and \$22.04m.
- ❖ Since the FTA was signed there was hardly any investment in Jordanian pharmaceutical manufacturing

Impact Projection of FTA with Colombia

(study conducted by PAHO)

- ❖ Measures relaxing Patentability criteria could imply an increase of **11%** in medicine prices in Colombia in 2020 -- impact of more than **240 million dollars**, equivalent to health-care expenditures for approximately 1.4 million people
- ❖ Measures for issuing patents for “new” uses could generate increase of **8%** in medicine prices -- impact of more than **180 million dollars**, equivalent to health-care expenditures for more than 1 million people
- ❖ Measures involving data protection would increase average medicine price by up to **30%**, equivalent to health-care expenditures for 3.8 million people

Total Impact:

- ❖ The impact on the total pharmaceuticals market is estimated at approximately **710 million dollars**
- ❖ The national industry could lose up to **71% of its market share**.

EU and FTAs

In October 2006 the EU commission launched its new trade policy called “**Global Europe** – competing in the world”

- ❖ **Market access** for European business due to elimination of tariff and non-tariff barriers,
- ❖ The so-called **Singapore issues** (investment, government procurement, competition and trade facilitation) which were rejected in Cancún by governments of the South,
- ❖ Intellectual property rights (**IPR**),
- ❖ The **service sector** which is a stronghold of the EU economy,
- ❖ A reference to sustainable development including rhetoric about **social and environmental standards, core labour rights**

EU-India FTA

Negotiations to be concluded by 2009 followed by a transition period of 7 years

Main issues regarding Access to Medicines:

- ❖ IP Issues – esp. Data Protection (Indian law does not allow for data protection/ exclusivity)
- ❖ Government Procurement (recent initiatives by Govt. to procure medicines at competitive rates for public sector may be under threat)

EU India FTA – Issues in Government Procurement

The discussions on procurement were disappointing. India is not yet politically or substantially ready to engage on the issues in this chapter, pending the outcome of the UNCTAD study and stakeholder consultations. The Indian side presented the preliminary conclusions of the UNCTAD study that pointed to a "net welfare loss" to India of a bilateral procurement chapter that included market access (UNCTAD study shows that if EU signs a Bilateral GPA with a country its exports to that country may increase by 12.7%.). The EC questioned the empirical basis of the study and requested to see the full version. India agreed to provide further comments on the EU's proposed approach before the 3rd round. The EC passed a strong message on the importance of a procurement chapter.

(EU Sectt. Notes on *Second round of EU-India FTA negotiations* . 1st-5th October, 2007, in Delhi)

EU India FTA – Issues in IP

Concerning IPR the Indian side showed a clear interest in the technical discussion but indicated political difficulties in engaging on substantive rules and enforcement in an agreement with the EU. It seemed clear that India sees the usefulness of IP for India's own right holders and showed a much more positive attitude towards IP including on enforcement than ever before (a clear shift in the approach). EC committed to provide for detailed presentations on GIs, unregistered designs and collective management at the coming round. It was also agreed that further examination of the different legislations will be required before any text proposals can be made.

(Second round of EU-India FTA negotiations . 1st-5th October, 2007, in Delhi)

In Lieu of a Conclusion

- ❖ Overall, bilateral agreements have been a disaster, for the developing countries and for the global trading system. ... These FTAs are creating a world in which there are two groups - the first consist of “my friends who can get in free” and the other, consist of countries that have to pay tariffs. So, it is a disaster.
- ❖ Secondly, bargaining between the United States and developing countries is not bargaining. Especially under the Bush (administration), it has been a take-it-or-leave-it situation.
- ❖ There are thousands of people dying in developing countries because of the trade agreements with the United States. They don't want to talk about it that way, but that is what is happening.

In Lieu of a Conclusion

- ❖ It's not about trading goods; it's about losing sovereignty. And it's about helping American drug companies. It's about America pushing for a particular agenda. It has not benefited any country. In fact, the free trade agreement with Mexico was the strongest, but the gap between Mexico and the United States increased in the first decade.
- ❖ They are not free trade agreements. They are not about free trade, but they are advantaged trade agreements. And they managed to advantage the United States at the cost of the developing countries.

Not my words but those of:

Joseph Stiglitz

Former Chief economist, World Bank

Thank You