Access to medicines and Intellectual Property Provisions in Free Trade and Economic Partnership Agreements

Flexibilities in International Intellectual Property Rules and Local Production of Pharmaceuticals for the Southern, Central and West African Region

7 – 9 December 2009, Cape Town, South Africa

David Vivas Eugui
dvivas@ictsd.ch
Access to medicines and IP provisions in FTAs

• The MFN clause in TRIPS and regional trade agreements
• Why industrialized and developing countries engage in FTA with IP provisions
• TRIPS Flexibilities and FTAs/EPAs
• Comparing IP provisions in recent FTAs/EPAs
• Assessing the impact: the case of Costa Rica and Dominican Republic
• Recommendations for negotiations
• Lessons from the assessment
THE MOST FAVORED NATION CLAUSE IN THE TRIPS AGREEMENT

• The legal nature of article 4 of TRIPS and its expansive effect
• Article 4d) of TRIPS only allows for the exemption of the MFN obligation to IP provisions adopted before 1995
• Some examples of Notifications under Article 4d) of TRIPS that cover subsequent laws, regulations or jurisprudence in the course of regional integration:
  ▪ Treaty of Rome
  ▪ The Cartagena Agreement
  ▪ Treaty of Asuncion
  ▪ NAFTA
WHY ARE COUNTRIES INTERESTED IN FTAS WITH IP PROVISIONS?

INDUSTRIALIZED COUNTRIES

- Protection of investments in new technologies
- Market access for high tech products
- The logic of the minimum floor of TRIPS
- Concerns over piracy in the digital environment and large scale counterfeiting
- Interest in global harmonization of IP law
Access to medicines and IP provisions in FTAs

WHY COUNTRIES ARE INTERESTED IN FTAS WITH IP PROVISIONS?

DEVELOPING COUNTRIES

- Consolidation of unilateral tariff preferences
- Need for commodities market access
- Investment expectations
- Interest in locking in market reforms
- Increased competition with other trade partners
- Security and aid concerns
- Decision comes from the highest political levels
<table>
<thead>
<tr>
<th>FLEXIBILITIES IN TRIPS</th>
<th>FTAs or EPAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom to define patentability criteria</td>
<td><strong>Limited in certain cases</strong>, i.e. industrial application has been defined as specific, substantial and credible utility (i.e. CAFTA)</td>
</tr>
<tr>
<td>Authorization to exclude certain subjects from patentability</td>
<td><strong>Limited in certain cases</strong>, such as “best efforts clauses” or direct obligations to make patents available to plants or animals (i.e. US-Morocco)</td>
</tr>
<tr>
<td>Possibility to exclude ‘new use’ from the definition of patents.</td>
<td>Limited – patents available to ‘new uses’ or “methods” in certain cases (i.e. US-Morocco)</td>
</tr>
<tr>
<td>Determination of the substantive grounds for the issuance of a compulsory license</td>
<td><strong>Limited to certain grounds</strong>, such as in cases of national emergencies, anti-trust remedies, and public non-commercial use (i.e. US- Jordan)</td>
</tr>
<tr>
<td>Determination of the exhaustion regime (national, regional, international)</td>
<td>Parties may limit <strong>parallel imports</strong> to cases where there is consent of the title holder (i.e. US-Morocco)</td>
</tr>
<tr>
<td>Option to protect undisclosed test data as protection against unfair competition</td>
<td>Limited, countries are obliged to provide for exclusivity of test data (i.e. US-CAFTA)</td>
</tr>
<tr>
<td>Measures against IPR abuses through competition laws</td>
<td>Similar as in TRIPS</td>
</tr>
<tr>
<td>Obligation to implement border measures against counterfeiting and piracy</td>
<td><strong>Obligations are widely expanded</strong>. They cover patents infringement as well as exports and goods in transit (i.e EU-Cariforum)</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>RATIFICATION OF THE PCT</td>
<td>√</td>
</tr>
<tr>
<td>PATENT RESTORATION TERM</td>
<td>√</td>
</tr>
<tr>
<td></td>
<td>At least 5 years</td>
</tr>
<tr>
<td>DATA EXCLUSIVITY FOR 5 YEARS</td>
<td>√</td>
</tr>
<tr>
<td>CONCURRENT TEST DATA PROTECTION PERIOD</td>
<td></td>
</tr>
<tr>
<td>LINKAGE BETWEEN PATENT PROTECTION AND MARKETING APPROVAL</td>
<td>√</td>
</tr>
<tr>
<td>CONDITIONAL USE OF COMPULSORY LICENSING</td>
<td></td>
</tr>
<tr>
<td>LIMITATIONS TO PARALLEL IMPORTS</td>
<td></td>
</tr>
<tr>
<td>STRICTER ENFORCEMENT MEASURES</td>
<td>√</td>
</tr>
<tr>
<td></td>
<td>(piracy and counterfeiting)</td>
</tr>
<tr>
<td>DOHA DECLARATION, P.6 DECISION /AMENDMENT</td>
<td>Side letter</td>
</tr>
</tbody>
</table>
Assessing the impact of TRIPS-plus

Findings from the Costa Rica case
(ICTSD/WHO/PAHO/UNDP/CINPE)

• By 2030, the price will increase between 18% and more than 40% yearly for covered active ingredients.

• There will be a need for increased public spending from about 2.008 to 3.357 million USD by 2030, depending on the scenario.

• Strongest impact per measure: patentability criteria (about 55% of the impact), data exclusivity (about 40%), linkage, and patent term restoration (about 5%).

• Concentration in the supply is putting at risk the sustainability of the universal access and procurement system.

• If the public budget is not increased, consumption will decrease by 24% in the worst-case scenario.

• By 2030, there will be a reduction between 24% to 27% in market share for the local generic industry.
Findings from the Dominican Republic case
(ICTSD/WHO/PAHO/UNDP/Fundacion Plenitud)

• There will be a **modest price increase of 9% to 15%** in absolute terms over covered AI by 2027.
• Strongest impact per measure: **data exclusivity (80% of the impact)**
• **Huge price differences between private and public markets** (80% of the purchases today are out-of-pocket).
• If the public budget does not increase, **consumption will decrease by 8%** in the worst-case scenario.
• There will be a reduction **of 14%** in the public market share and **24%** in the private market for local generic industry by 2027.
• **Information asymmetries and government imperfections, have a higher impact on prices than regulatory changes in intellectual property.**
Some recommendations regarding negotiations of IP provisions in FTA/ EPAs

- Understand the importance of the MFN clause of TRIPS;
- Negotiate to the extent possible with your region and not bilaterally;
- Coordinate internally with relevant authorities: Ministries of health, sanitary authority, IP offices, customs officials;
- Consult with all relevant stakeholders. They can be of great assistance during the negotiations or implementation phase;
- Assess carefully any economic (trade offs) and public health (possible costs) impact of new IP provisions on health.
Some recommendations regarding negotiations of IP provisions in FTA/ EPAs

• Keep TRIPS flexibilities to a maximum;
• Seek balance in the IP text itself (innovation, biodiversity, traditional knowledge, technology transfer, competition policy, etc.)
• Make text proposals. Do not wait to get highest demands from your counterparts;
• The Cariforum experience seems to be a useful example, with the exception of the section on IP enforcement (too burdensome).
Some lessons regarding the impact assessment of IP provisions on public health

• The greater concentration in supply, accompanied by high standards of IPR protection, the greater the need to generate a concentration in demand in order to be able to negotiate prices.

• Do not underestimate the effect of Information asymmetries and market and government imperfections on prices.

• Using TRIPS as well as US-CAFTA flexibilities can make a difference.

• We need to explore the value of regional procurement: A potential deal between Haiti and Dominican Republic could enable the use of a regional procurement system in line with the P.6 Decision.
Assessing the impact of TRIPS-plus

Some lessons regarding the assessment impact on IP provisions on public health

• Mitigation policies can have a positive effect. Some of the most effective ones include:
  – Social security systems
  – Subsidies to consumers
  – Strategic use of government procurement
  – Competition policy and law
  – Medicine and drug regulation (regulation of medical prescription and pharmacy practices)
  – Information to consumers about prices and competitive products.
Thanks for your attention

www.ictsd.net