The Latin American Pharmaceutical Sector

Legal and Commercial Trends in the Post-TRIPS Environment

Cassandra Sweet, PUC-Chile & Andrea Laplane, ECLAC

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Part I

Legal Trends

A. Overview
B. Institutional responses
In dispute:

- Implementation
- Interpretation

Defining IPR Systems
A. Overview

Areas of continuing legal conflict

<table>
<thead>
<tr>
<th>Strategies</th>
<th>Examples</th>
<th>Cases</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Evergreening</td>
<td>&gt; spurious patents</td>
<td>Pfizer</td>
<td>Chile</td>
</tr>
<tr>
<td></td>
<td>&gt; applications for the extension of patent validity (pipeline)</td>
<td></td>
<td>Brazil</td>
</tr>
<tr>
<td></td>
<td>&gt; application for the extension of patent validity (reformulations/recombinations)</td>
<td>Bristol Myers Squibb, Novartis, Pfizer, Merck, AstraZeneca</td>
<td>Argentina, Mexico</td>
</tr>
<tr>
<td>2 Breaking Bolar Rights</td>
<td>&gt; allegation of illegitimate use of confidential information</td>
<td>MSP Singapore Co., Schering, Novartis</td>
<td>Argentina</td>
</tr>
<tr>
<td>3 Fear campaigns</td>
<td>&gt; negative publicity on the quality of generic medicines</td>
<td></td>
<td>Chile</td>
</tr>
<tr>
<td></td>
<td>&gt; letters warning local laboratories about pending patent applications</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
B. Institutional Responses

Heterogeneity

- States
- Multinationals
- Local firms
B. Institutional Responses

Examples

Brazil
- Active policies
- Different frames:
  - Public health
  - IPRs
  - Sanitary security
  - International trade
  - Antitrust

Chile
- System under construction
- Local laboratories have obtained favorable decisions in Courts.

Mexico
- Different configuration
- SCNJ’s recent resolution allows for the extension of patent’s validity
Part II

Commercial Trends

A. Macro Picture
B. Innovation and Capacity Index
C. Selected Country Cases
D. Synthesis
A. Macro Picture

Leading Latin American Pharmaceutical Markets

Source, IMS Health, 2008
A. Macro Picture

Pharmaceuticals as % of healthcare spending

Source, World Bank, 2007
A. Macro Picture

Finished Formulation Imports for Select Countries in Latin America 1998-2007

Source, UN Comtrade Data, 2008
A. Macro Picture

API Imports for Select Countries in Latin America 1998-2007

Source, UN Comtrade Data, 2008
A. Macro Picture

% of Imports, Bulk Chemicals and Medicines, 2008

Source, UN Comtrade Data, 2008
B. Innovation and Capacity Index

Mapping Capacity in Pharmaceutical Production

Stage 1: Innovation/Know-how
Stage 2: Bulk Materials
Stage 3: Finished Formulation Assembly
Stage 4: Registration & Delivery

Patent Path
1. R&D
   2. Discovery
1. APIs
   2. Intermediates
   3. Incipients
1. Formulation
   2. Packaging
1. Regulatory approval

Skill
Innovative Capacity → Organic Chemistry → Production Scale → Marketing

Generic Path
1. R&D
   2. Reverse synthesis
1. APIs
   2. Intermediates
   3. Incipients
1. Formulation
   2. Packaging
1. Bio-disponability
   2. Bio-Equivalency
   3. Regulatory Approval
B. The IICI

IICI Score

Innovation & Capacity Indices

Output/Input Indices

Area Indices

1) Total patents* applied
2) Total patents granted*
3) % of national patents
4) Publication and knowledge transfer*
5) Commercialization of IP*
6) R&D investment total
7) R&D as a percent of sales

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2) Total patents granted*
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7) R&D as a percent of sales

*Weighted per 100,000 pop.
C. Selected Country Cases: Argentina

Percent Share of Sales in Argentinean Pharmaceutical Market, 2004-2008

- Top 15 national firms account for 43.9% of total market
- High level of generic production
- 3 of top 5 firms of national capital

<table>
<thead>
<tr>
<th>Company</th>
<th>Sales, US$</th>
<th>Country</th>
<th>Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roemmers</td>
<td>308</td>
<td>Argentina</td>
<td>8.20%</td>
</tr>
<tr>
<td>Bago</td>
<td>198</td>
<td>Argentina</td>
<td>5.30%</td>
</tr>
<tr>
<td>Bayer</td>
<td>183</td>
<td>Germany</td>
<td>4.90%</td>
</tr>
<tr>
<td>Ivax</td>
<td>152</td>
<td>Isreal</td>
<td>4.10%</td>
</tr>
<tr>
<td>Elea</td>
<td>149</td>
<td>Argentina</td>
<td>4.00%</td>
</tr>
</tbody>
</table>

Fuente: Instituto Nacional de Estadística y Census, 2009
C. Selected Country Cases: Argentina

El mercado de APIs

- Argentine firms produce over 15 percent of APIs inserted into the local pharmaceutical production chain.
- 2nd source of APIs in Argentina are those which are imported from India.
C. Selected Country Cases: Brazil

Trade Deficit, 2005-2008

- Brazilian firms have high levels of generic manufacture
- 5 firms account for 66% of generics market
- Low API production
- Trade balance has deteriorated in recent years
C. Selected Country Cases: Brazil

High Import Value

<table>
<thead>
<tr>
<th>Rank</th>
<th>Item</th>
<th>% of Total Imports</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Vehicles other than railway</td>
<td>18.16</td>
</tr>
<tr>
<td>2</td>
<td>Pharmaceutical Chain</td>
<td>17.90</td>
</tr>
<tr>
<td>3</td>
<td>Fertilisers</td>
<td>13.12</td>
</tr>
<tr>
<td>4</td>
<td>Organic chemicals</td>
<td>11.87</td>
</tr>
<tr>
<td>5</td>
<td>Plastics and articles thereof</td>
<td>8.13</td>
</tr>
<tr>
<td>6</td>
<td>Pharmaceutical products</td>
<td>6.04</td>
</tr>
<tr>
<td>7</td>
<td>Rubber and articles thereof</td>
<td>4.71</td>
</tr>
<tr>
<td>8</td>
<td>Iron and steel</td>
<td>4.69</td>
</tr>
</tbody>
</table>
C. Selected Country Cases: Ecuador

Low national production

- Ecuadorian market has low generic penetration
  - 93.95% of market de marca
  - 6.05% of market genericos

Source, ECV, 2009
D. Synthesis

Innovation and Capacity Index

[Diagram showing a scatter plot with countries such as Brazil, Argentina, Colombia, Costa Rica, Uruguay, Ecuador, Peru, Guatemala marked on it.]
### D. Synthesis

Levels of Production in Global Context

**Deep**—US and European firms….

**Medium**—Asian firms….

**Shallow**—Latin American firms...

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discovery</td>
<td>Industrial Scale</td>
<td>Synthesis of APIs</td>
<td>Packaging</td>
</tr>
<tr>
<td>Pre-clinical</td>
<td>API Production</td>
<td>Formulation of dosis</td>
<td>Marketing</td>
</tr>
<tr>
<td>Clinical</td>
<td>Intermediate Production</td>
<td></td>
<td>Distribution</td>
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