Aarhus Convention – Meeting of the Parties
Task Force on Access to Information

Test Data Protection in TRIPS

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Art. 39: Undisclosed Information (1)

- Undisclosed information = information that:
  - Is secret, i.e.
    - not generally known
    - not readily accessible,
  - has commercial value because it is secret, and
  - is subject to reasonable steps under the circumstances to keep it secret.

- Link to Article 10\textsuperscript{bis} of the Paris Convention (protection against unfair competition)
  - Any act of competition contrary to honest practices constitutes act of unfair competition
Art. 39: Undisclosed Information (2)

- Rights conferred: possibility for natural and legal persons lawfully in control of undisclosed information of preventing unauthorized disclosure, acquisition or use of that information by others in a manner contrary to honest commercial practices

- “contrary to honest commercial practices” includes at least
  - breach of contract
  - breach of confidence
  - inducement to breach
  - acquisition by third parties who knew or should have known such practices were involved in the acquisition
Art.39.3: Test Data Protection (1)

- Obligation arises when
  - Members require submission of undisclosed test or other data
  - the production of which involves considerable efforts
  - as a condition of granting marketing approval
  - for pharmaceuticals or agricultural chemicals using new chemical entities

- Members are obliged to protect such data against:
  - unfair commercial use
  - disclosure, unless:
    - disclosure is necessary to protect the public, or
    - steps have been taken to protect the data against unfair commercial use
## Transitional Arrangements
(for application of the TRIPS Agreement)

<table>
<thead>
<tr>
<th>Year</th>
<th>Industrialised Countries</th>
<th>DCs and Economies in Transition&lt;sup&gt;1)&lt;/sup&gt;</th>
<th>DCs products not patented</th>
<th>LDCs pharma (patents &amp; previously test data), EMRs waived</th>
<th>LDCs 1)</th>
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<tbody>
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<td>1996</td>
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1) National treatment and MFN treatment obligations apply as of 1996
Art.39.3: Controversial discussion on implementation

- Consultations under WTO DS mechanism between US and Argentina (WT/DS171/1 and WT/DS/196/1):
  - protection of test data for pharmaceuticals and agrochemicals was raised among other issues
  - mutually agreed solution notified to DSB according to which
    - differences in interpretation shall be solved under DSU rules
    - Parties will continue consultations to assess progress of legislative process in Argentina
Wide variety of practice among Members:

2 examples
EU: Data Exclusivity (1)

8+2(+1) exclusivity formula

**Data Exclusivity**
- **8 years**
  - Marketing authorisation of reference product

**Market Protection**
- **2 years**
  - Generics application
- **(1 year)**
  - Generics launch (no new patent)
  - OTC/WEU new indication
    * study data only

**Data Exclusivity**
- **1 year**
  - Assessment – MA granted
  - MRP Pricing & Reimbursement
  - Prepare to Launch
  - Extra market protection if new indication is registered in first 8 years and brings significant clinical benefit over existing therapies

Submitted since November 2005
Argentina: unfair competition

- Confidentiality Law No. 24.766 and Executive Order No. 150/92
  - Abridged approval of medicines similar to those already registered in selected countries or Argentina
  - No test data required to be submitted in Argentina

- Novartis Pharma AG v. Monte Verde SA & Varios Propiedad industrial e intellectual (Case 5.619/05 – 2011)
  - Glivec approved in US and Europe, not patented in Argentina
  - Federal Appeals Court rejected Novartis claim, arguing *inter alia* that:
    - neither plaintiff nor defendant had filed the data in question in Argentina,
    - TRIPS 39.3 permitted national authorities’ relying on existing data in order to analyse a second or future application related to the same product, and that this was not “unfair commercial use”.
WTO Accessions Working Party Reports

● Binding commitments:
  ● data exclusivity: at least 6 years for pharmaceuticals and agrochemicals (China)
  ● data exclusivity: 5 years for pharmaceuticals, 10 years for agrochemicals (Ukraine)

● Descriptive part of the report:
  ● data exclusivity: 5 years for pharmaceuticals and agrochemicals (Saudi Arabia, Tonga, Viet Nam)
  ● Documents on pharmaceuticals and medical products to be treated as trade secrets (Croatia)
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