Regulatory Framework of Test Data
WIPO Symposium
Geneva, 8 February 2010

Test Data Protection:
The WTO Perspective

Roger Kampf
Counsellor, WTO Secretariat

I. Introduction

- Context
- Subject Matter
- Conditions
- Obligations

Test Data Are …(1)

- General term for data resulting from clinical trials for pharmaceuticals and tests of agrochemicals
- Stand alone IPR category
- Integral part of broader category of undisclosed information to be effectively protected against unfair competition

Test Data Are …(2)

- **Distinct from patents:**
  - **certain linkages: conceptual, regulatory**
  - **but: two different subject matters of protection (patents – innovation; test data – investment)**
  - **different parties may own different rights**
  - **protection to be provided irrespective of patent on products concerned**
  - **compulsory licences under Art. 31 TRIPS *per se* not applicable**

Interests Involved

- **Of different players:**
  - **originator**
  - **competitor**
  - **public**
- **Economic relevance of test data protection, for example, where:**
  - **medicine is not patent-protected**
  - **medicine benefits only from short remaining period of patent protection**
  - **patent is difficult to obtain (e.g. biologicals)**

Test Data Protection: Subject Matter / Conditions

- **Obligation arises when:**
  - Governments/governmental agencies require submission
  - of undisclosed test or other data
  - for marketing approval
  - of pharmaceutical or agricultural chemicals
  - using new chemical entities
  - and the production of such data involved considerable efforts
- **Key terms (underlined above) not defined**

Types of Obligations

- **Protection against unfair commercial use:**
  - involves more than merely keeping data secret
  - key terms not defined:
    - unfair
    - commercial
    - use
  - link to Paris Conv.
  - need to balance interests involved

- **Prohibition of disclosure**
  - Unless necessary to protect public or steps have been taken to protect against unfair commercial use

    → scope of "to protect public"

    → application of necessity test

    → term of protection of confidentiality not defined - as long as data are undisclosed

II. How to Protect Test Data

- Issues Raised
- Negotiating History
- Interpretation / Application
- Country Practices
- FTAs
- WTO Accessions

How to Protect Test Data ?

- **Does TRIPS provide the answer:**
  - **no, it remains silent on how to implement relevant obligations**
- **Have issues been raised in past debates:**
  - **yes, overview of points made in TRIPS Council**
- **Are there tools available to help answering the question:**
  - **negotiating history**
  - **interpretations**
- **Do other sources provide information:**
  - **International / regional organizations**
  - **experiences from country practices, FTAs, WTO accessions**

Issues Raised in WTO (1)

- **General:**
  - **need for further clarification: seemed to be the feeling in 2001 (EC, India, Honduras), but no discussion at this stage**
  - **conserve existing flexibility (African Group et alia)**
  - **distinguish between protection of patents and test data (EC)**

Issues Raised in WTO (2)

- **How to protect against « unfair commercial use »:**
  - **data exclusivity for reasonable period is the most effective way (EC, US, Japan)**
  - **there is no requirement to grant exclusive rights to owner of test data (African Group et alia, India)**
  - **competent authority can rely on originator data to assess second application for the same drug (African Group et alia)**

Issues Raised in WTO (3)

- **Definition of new chemical entity:**
  - **does not cover new dosage or use (African Group et alia)**
- **Link with other TRIPS provisions:**
  - **need to avoid that test data protection weakens rights under other TRIPS provisions, such as accelerated procedures to grant CL under Article 31(b) (EC, India, Dominican Republic)**
  - **should not override rights under other provisions; undisclosed information must be accessible at least in situations of national emergency or circumstances of extreme urgency (Cuba)**

Negotiating History

- **Chairman's report on status of work in the Negotiating Group, July 1990:**
  - **proponents of approach B do not accept the protection of trade secrets as a category of IP**
- **Brussels draft, December 1990:**
  - **« (…) [Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable period of time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation] (…) ».**
- **Neither approach is reflected in final version of Article 39.3 TRIPS**
- **Could provide some background to meaning of « considerable efforts »**

Interpretation / Application

- No WTO jurisprudence or authoritative guidance
- DS consultations between US and Argentina (WT/DS171/1 and 196/1):
  - raised test data protection among other issues
  - mutually agreed solution notified to DSB in 2002:
    - differences in interpretation shall be solved under DSU rules
    - further consultations to assess progress of legislative process in Argentina
    - no follow-up notified to WTO since 2002
- But: application of pro-public health interpretation in the Doha Declaration covers TRIPS as a whole
- Importance of ongoing policy debate for interpretation
- Note: Extension of transition period for LDCs until 2016 also applies to undisclosed information

Other Sources (1)

- **WHO:**
  - **Commission on IPRs, Innovation and Public Health: Art.39.3 does not create property rights, nor a right to prevent others from relying on the data (…) except where unfair (dishonest) commercial practices are involved**
  - **bracketed text in draft GSPOA (see document WHA A61/9): « avoid restrictions for the use of or reliance on undisclosed test data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS »**
  - **no specific reference retained in final GSPOA**
- **WIPO:**
  - **legislative advice: « flexibilities on test data may go from establishing a regime of right-to-remuneration (as opposed to one of exclusivity) to the adoption of exceptions and limitations to rights conferred»**

Other Sources (2)

- **OECD:**
  - **Recommendation on Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals 1983: need to protect data from unauthorised use in notifications of new chemicals**
- **FAO / International Code of Conduct on the Distribution and Use of Pesticides:**
  - **Council Resolution 10/85: protection of proprietary rights to use of data → should neither be divulged nor used to evaluate submissions by other applicants**
  - **Council Resolution 1/123: revised version no longer refers to proprietary rights**
  - **Guidelines for the registration of pesticides**

Related Areas

- **Agrochemical products:**
  - **explicitly covered by Article 39.3 TRIPS**
  - **often treated differently in domestic legislation, in particular through longer period of data exclusivity, caused by different requirements / conditions (repetitions required, toxic nature, continuing data generation, costs, large number of safety tests, small approval rate)**
  - **different rules of fairness apply to different sectors**
- **Biosimilars:**
  - **not specifically addressed by TRIPS**
- **Not currently discussed in TRIPS Council**

Country Practices: General

- **Variety of implementation models demonstrates that:**
  - **reflection as to how IPRs are best managed at country level is taking place**
  - **TRIPS flexibilities are used**
- **Differences namely with respect to exclusivity periods, ranging from:**
  - **no specific period defined (majority of developing countries / LDCs)**
  - **5 to 8 years of exclusivity (some developing countries, US, Australia, New Zealand, Canada)**
  - **10 years of exclusivity (EU, EFTA, CH)**

Country Practices: Examples (1)

- **EU, US:**
  - **data exclusivity: at least 5 years for pharmaceuticals / 10 years for agrochemicals**
  - **can be extended for new indications / formulations**
  - **special rule EU: possibility to waive test data protection for exports of products manufactured under Para.6 System**
- **Turkey: term of six year exclusivity limited to duration of patent**
- **India:**
  - **currently no specific law to protect test data**
  - **Satwant Reddy Committee recommendations (2007)**

Country Practices: Examples (2)

- OAPI / Bangui Agreement, Annex VIII, Art.6: merely reiterates Art.39.3 TRIPS
- Andean Pact:
  - Art.266 of Decision 486 repeats Art.39.3 TRIPS, expressly allowing its members to take steps to guarantee protection
  - but: Andean Court ruled in 2005 that data exclusivity violated IP norms
- Argentina:
  - 10 years data exclusivity for agrochemicals revoked in 1998
  - at present: non-exclusivity model
- Brazil:
  - pharmaceuticals for human use: general law on protection against unfair competition
  - pharmaceuticals for veterinary use, fertilizers, etc. - Law 10,603 (17-12-2002):
    - provides for 10 years data exclusivity for products based on new chemical entities and 5 years for additional data required by regulatory authority;
    - allows CL

Provisions in FTAs (1)

- **Some selected examples:**
  - **establishment of data exclusivity: 5/10 years from the date of domestic approval, plus (in some cases) additional three years for new clinical information**
  - **definition of new pharmaceutical product = not previously approved in the Party**
  - **marketing approval not to be granted for same or similar products**
  - **limited reliance on foreign approval**
  - **term of protection independent of patent term**
  - **but: not to be enforced to protect public health in accordance with Doha Declaration**
  - **compensation scheme instead of data exclusivity admitted**
  - **mere confirmation of Art.39 TRIPS**

Provisions in FTAs (2)

- Role of national implementing legislation:
  - ex.: no protection if product not marketed domestically within 1 year after approval or registered abroad for more than 1 year
- WTO's role as a member-driven organization is limited:
  - TRIPS: Members are free to adopt higher standards
  - At best: monitor FTA content and offer platform for discussion
  - Competent bodies: TRIPS Council, Committee on Regional Trade Agreements, Trade Policy Review

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)
  - Registration of generic products not foreseen (Cap Verde)
  - Documents on pharmaceuticals and medical products to be treated as trade secrets (Croatia)
- **WTO's role**

Conclusions

- Public goods vs. proprietary data: test data are of public interest, but generated by private investment → need to optimize originator companies' interest to produce data and public benefit from their use
- TRIPS does not define key terms: no uniform implementation model how and under what conditions to protect test data
- Variety of national legislations, ranging from data exclusivity through compensation to mere protection of data against acquisition by dishonest means
- WTO Members have flexibility to take decision at country level that reflects individual needs → key role of domestic legislator
- Decisions typically guided by domestic considerations and international context
- Currently not discussed in TRIPS Council

Some References

- Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)DEC/2)
- Special discussion on IP and Access to Medicines (IP/C/M/31)
- Communication from the EC and their member States on the relationship between the provisions of the TRIPS Agreement and access to medicines (IP/C/W/280)
- Submission by the African Group et alia on TRIPS and public health (IP/C/W/296)
- Statement by the Cuban Delegation on IP and access to medicines (IP/C/W/299)