The Protection of Test Data

A Development Perspective

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Overview of Presentation

- Scope of presentation
- Impact of test data protection in developing countries
  - Local generic producers
  - Availability of medicines
- Development-oriented approaches to test data protection
- Conclusions

Scope of presentation

- Article 39.3, TRIPS Agreement: test data related to the marketing approval of
  - Pharmaceutical products
  - Agricultural chemical products
- Involves different stakeholders and different public interests
- This presentation focuses on test data related to the marketing approval of pharmaceutical products

Test Data Protection - Impact in Developing Countries

- Protection provides important economic incentive for originator companies
- For DCs and LDCs, this incentive is of limited value:
  - Most originator companies are OECD country-based
  - Low level of capacity in DCs and LDCs to develop new drugs

Test Data Protection - Impact on Developing Countries' Producers

- Many DCs and some LDCs have some capacity to produce generic versions of originator products
- Public health perspective: generic competition is desirable as it may contribute to significant drugs price decreases (CIPIH Report 2006)
- Depending on the type of data protection regime, market entry by generic producers may be seriously delayed

Test Data Protection - Impact on Developing Countries' Access to Medicines

- Delay of generic competitors' market entry will likely lead to higher drug prices
- Many DCs lack safeguards to mitigate impact
  - Competition law & policy (excessive prices)
  - Insurance coverage/social security systems
  - Effective systems of price control (establishing upper price limits)
- Need in DCs to implement data protection from a public health perspective

Development-oriented approaches to test data protection (1)

- Basic considerations for developing countries:
  - Importance of generic competition for drugs availability
  - Limited value for local producers of incentives triggered by data protection
  - Originator companies recoup bulk of their R&D costs in OECD markets

Development-oriented approaches to test data protection (2)

- Basic policy line for developing countries: seek to promote generic competition
- Legal options depend on domestic regime of test data protection
  - Exclusive rights
  - Protection against misappropriation
  - Compensatory liability regimes

Basic impact of data exclusivity regimes (1)

- Exclusive rights prevent, during fixed amount of time, reliance by DRA on originator's data for purpose of approving generic drugs
- Protection independent of patent status → new layer of exclusive rights
- Generics producers often lack financial means to produce own test data → will be barred from market entry during exclusivity period

Basic impact of data exclusivity regimes (2)

- Impact is felt where
  - No patent on protected product
  - Term of exclusivity lasts longer than term of patent protection (long drug development cycle)
  - A compulsory license (CL) is granted on the patented product: licensee cannot afford producing own test data → no marketing approval → CL useless

Development-oriented approaches to data exclusivity (1)

- Chilean implementation of the US – Chile FTA: no exclusive rights in cases of
  - Anticompetitive behavior
  - Overriding interests of public health, non-commercial public use, etc.
  - No commercialization in Chile of product within 12 months from registration
  - Product has a registry in foreign country of more than 12 months
  - Criticized by USTR → Chile on 2007 Priority Watch List

Development-oriented approaches to data exclusivity (2)

- Model Law on the Implementation of Test Data Protection under the US-DR/ CAFTA (ICTSD-UNCTAD Regional Research Agenda)
  - Scope of protection does not extend to new uses or indications of chemical entities
  - Test data exclusivity cannot be invoked against compulsory licensee
  - Exclusive rights may be revoked, e.g. in case of anti-competitive conduct or public interest reasons
  - Interested third parties may request revocation/rectification/suspension

Alternative to data exclusivity: misappropriation regime

- Protection of test data against appropriation by competitors through unfair commercial means (e.g. fraud)
- No protection against reliance by DRA on originator's data for approval of generics
- Considerably facilitates generic market entry
- TRIPS negotiating history of Article 39 suggests that misappropriation approach is TRIPS-compatible (controversial)
- Rejection by OECD countries limits practical value of this approach for developing countries

Alternative to data exclusivity: compensatory liability regime (1)

- No exclusive rights
- Generic producers may rely on data for approval purposes
- Originator may claim compensation based on
  - Cost of producing the data
  - Proportion of global market share obtained by generic producer
  - Example: generic approval for a national market representing 5% of global market → compensation of 5% of cost of data production

Alternative to data exclusivity: compensatory liability regime (2)

- Advantage: higher acceptance by OECD countries, as originators receive compensation
- US applies comparable system to agricultural chemical data (after exclusivity period)
- Disadvantage: originator companies recoup bulk of R&D investment in OECD markets → no justification to obligate DC-based users of data to pay extra compensation

Conclusion

- DCs need to promote access to medicines through (*inter alia*) generic competition
- Test data exclusivity may seriously delay generic market entry
- DCs must be aware of flexibilities within data exclusivity regimes to mitigate impact
- TRIPS allows non-exclusive alternatives

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