UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

Test Data Protection – The UNCTAD Perspective

WIPO Symposium on the Evolution of the Regulatory Framework of Test Data – From the Property of the Intellect to the Intellect of Property

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Overview of Presentation

- Scope of presentation
- Protection under TRIPS & implications
- Data exclusivity in FTAs & implications
- Linkage provisions in FTAs & implications
- 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
- Focus on test data related to the marketing approval of pharmaceutical products

What are pharmaceutical test data?

- Data proving safety & efficacy of medicines
  - Pre-clinical trials on computers, animals
  - Clinical trials on humans
- Clinical data submitted to drug regulatory authority (DRA) for marketing approval
- Distinguish regulatory – patent issues
  - Trials are subsequent to patent grant
  - Trials require financial & administrative effort
  - But not necessarily creativity/intellectual effort

Protection of test data under TRIPS Art. 39.3

- Origination of test data may require considerable (non-intellectual) efforts
- Significant commercial value (marketing approval)
- Those data shall be protected, *inter alia* against « unfair commercial use »
  - Disclosure by DRA to competitors
  - Espionage by competitors

Test data and generic producers

- Clinical trials too expensive (no patent to recoup costs)
- Cheaper to show bioequivalence
  - Same amount of active ingredients in same amount of time as originator drug
  - Safety & efficacy already proven by originator → DRA reliance (controversial)
- Rapid marketing approval

Reliance - some implications

- Early marketing approvals: checks & balances on weak patents
  - Regulatory approval independent of patent status of originator drug → Need for patent holder to enforce his IPR
  - Generic competitor may challenge weak patent as defense in litigation
  - Important number of weak pharmaceutical patents
    - 73% success rate of patent challenges in US courts (2002): FTC study
    - 62% success rate of patent challenges in EU courts (2000-2007): EU Commission Pharmaceutical Sector Inquiry

Protection of test data under FTAs (1)

- US FTAs (e.g. Chile; DR-CAFTA; Peru); EU proposals to Colombia, Ecuador, Peru, India: exclusive rights in test data
- Rationale for IP protection
  - Incentives for innovation & creativity
  - Data exclusivity: incentive for investment
  - Property of intellect → intellect of (creating non-intellectual) property
- Impact on generic competition: no bioequivalence during term of protection → full clinical trials dossier

Protection of test data under FTAs (2)

- US FTAs: 5 years from marketing approval (US-Peru more flexible; EU Andean proposals: 10 years + 1 for new indications)
- Even if originator only has foreign approval
- Plus 5 years after domestic approval = max 10 years
  - Exception: US-Peru
- Even for off-patent substances

Example: Implementation of data exclusivity (DE) in Chile

- Termination of DE if no domestic commercialization of product within 12 months after domestic approval
- No DE if no domestic application for approval within 12 months from first approval in any other country

DE: General Implications

- Delays in marketing approvals (only after expiry of DE)
- Loss of important opportunity to challenge poor quality patents
  - No marketing of generics prior to DE expiry
  - Lower motivation to challenge weak patents: DE as additional barrier

Implications for public health (1)

- In case of compulsory licensing (CL)
  - Need for marketing approval
  - CL applies to patent only, not to DE
  - Example EU legislation:
    - specific exception from DE in case of draft Art 31*bis* exports
    - but no other exception
  - US-Peru FTA, EU proposals: subordinate DE to Doha Declaration/right to protect public health

Implications for public health (2)

- In case of regulatory review (« Bolar ») exception:
  - Use of patented substance to submit generic copy to DRA
  - But DRA cannot approve before expiry of DE
  - → no legal security for generic producer
  - → chilling effect on investment decisions
  - → late market entry
  - May diminish effect of regulatory review exception

Linkage provisions in FTAs (1)

- Marketing approvals by DRA are based on criteria of safety & efficacy
- No need (and often no capacity) to check patent status
  - IPRs = private rights, including enforcement
- Introduction of linkage in most US FTAs: no approval during patent term, unless consent
  - DRA is turned into IP enforcement agency

Linkage provisions in FTAs (2)

- Public health concerns: effect on CLs and Bolar exception
  - comparable to DE: no approval without patentee's consent
- US-Peru; US-Colombia; US-Panama: linkage optional
  - Instead: effective remedies for patent infringement litigation
  - Peru's implementing legislation: *Decreto Legislativo 1074 of 28 June 2008*

Linkage: Implications

- Mandatory linkage means DRA (rather than IP holder) enforces patents → reduced risk of negative finding by court on weak patents
- US-Peru; US-Colombia; US-Panama: primary responsibility of IP enforcement back on IP holder

Conclusions

- TRIPS permits various forms of data protection (exclusive/non-exclusive)
- TRIPS permits distinction between regulatory issues and patent law
  - Safety & efficacy are decisive for drugs approval
  - Private enforcement of private IPRs
- FTAs: DE & linkage with patent status
  - DE: exclusive rights in non-intellectual assets
  - Linkage means public assistance in enforcement of private IPRs
  - Impact on generic competition & poor quality patents

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