Protection of pharmaceutical test data under TRIPS and FTAs

Christoph Spennemann, Legal Expert
Intellectual Property Unit
Division on Investment and Enterprise
UNCTAD
Overview of Presentation

- What are pharmaceutical test data?
- Protection under TRIPS & implications
- Data exclusivity in FTAs & implications
- Linkage provisions in FTAs & implications
- Conclusions
What are pharmaceutical test data?

- Data proving safety & efficacy of medicines
  - Pre-clinical trials on computers, animals
  - Clinical trials on humans
- Submission to drug regulatory authority (DRA) for marketing approval
- Distinguish regulatory – patent issues
  - Trials are subsequent to patent grant
Protection of test data under TRIPS Art. 39.3

- Origination of test data may require considerable 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
Implications for generic producers

- Clinical trials too expensive (no patent like data originator)
- 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
Some other implications

• Early marketing approvals increase likelihood of patent infringement litigation
  • Regulatory approval independent of patent status of originator drug
  • Need for patent holder to enforce his IPR
  • Important opportunity for generic competitors to challenge poor quality pharmaceutical patents
    • 73% success rate of patent challenges in US courts (2002)
    • 62% success rate of patent challenges in EU courts (2000-2007)
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

- Generic industry: no bioequivalence during term of protection → full clinical trials dossier
Protection of test data under FTAs (2)

- 5 years from marketing approval (US-Peru more flexible; EU: 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
General Implications

- Delays in marketing approvals (only after expiry of DE)
- Loss of important opportunity to challenge poor quality patents
  - Less patent infringement litigation
  - Patent enforcement made easier through DE
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 31bis 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 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
  • Strictly speaking, no test data issue
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
Implications

• Mandatory linkage means DRA (rather than IP holder) enforces patents → less patent infringement suits

• US-Peru; US-Colombia; US-Panama: primary responsibility of IP enforcement back on IP holder
Conclusions

• Test data have commercial value → need for protection

• TRIPS permits distinction between regulatory issues and patent law
  • Safety & efficacy are decisive for drugs approval
  • Private enforcement of private IPRs

• FTAs introduce new exclusive rights in test data and link regulatory and patent issues
  • Not only safety & efficacy determine drugs approval
  • Public assistance in enforcement of private IPRs
  • Impact on generic competition & poor quality patents
Contact

Christoph Spennemann
Legal Expert
Intellectual Property Unit
Division on Investment and Enterprise (DIAE)
UNCTAD
E-mail: Christoph.Spennemann@unctad.org
Tel: ++41 (0) 22 917 59 99
Fax: ++41 (0) 22 917 01 94
http://www.unctad.org/tot-ip