TRIPS Post-Grant Flexibilities: Key Exceptions to Patent Holders' Rights

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OVERVIEW OF PRESENTATION

- Patent holders’ rights
- Article 30 TRIPS Agreement on patent exceptions
- The scientific research/experimental use exception
- The early working/Bolar exception
TRIPS Post-Grant Flexibilities: Key Exceptions to Patent Rights

Patent holder’s rights (TRIPS Article 28.1)

• Right to exclude others (negative right), for at least 20 years, from the acts of:
  – making,
  – using,
  – offering for sale,
  – selling,
  – or importing a protected product
General exceptions (TRIPS Article 30)

• Members may provide *limited exceptions* to the exclusive rights conferred by a patent, provided that:

  – such exceptions do not *unreasonably conflict* with a normal *exploitation* of the patent
  – and do not *unreasonably prejudice* the *legitimate interests of the patent owner*,
  – taking account of the *legitimate interests of third parties*. 
TRIPS Article 30 – Implementation

• Text is vague, many undefined terms
• Criteria is cumulative
• Both Developed and developing country patent laws provide a variety of patent exceptions in areas where public interest is considered superior to interests of the patent holder
• Distinguish
  – exceptions to patentability: natural substances; methods of medical treatment (see above): no patent can be granted
  – patent exceptions (Art 30): patent granted, but rights restricted afterward
TRIPS Article 30 in public health context

- Two relevant exceptions in developed country laws:
  - Scientific research/experimental use exception
  - Early regulatory working («Bolar») exception
Scientific research/experimental use exception

• TRIPS Art 7: «The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology...»

• **Follow-on innovation** depends on (often patented) existing know-how→need for scientists to have free access for product/process for improvement without infringing patents

• Need for experimental use exception
Scope of experimental use exception in developed countries (1)

- Acts done for **purely scientific purposes**
- Different approaches as regards **acts done for commercial purposes**:
  - **Australia** (suggested provision): «the existence of a commercial purpose or objective does not preclude the application of the exemption»
  - **Germany** (Supreme Court): the mere fact that there might be some ultimate commercial consequences does not preclude the application of the experimental use exception»
  - **USA** (Court of Appeals for the Federal Circuit): extremely narrow research exception: limited to acts of amusement, idle curiosity, or strictly philosophical inquiry
Scope of experimental use exception in developed countries (2)

• Switzerland (2008 Patents Act):
  – Exception includes experiments « on » patented substance even with commercial objective, provided main objective is generation of new knowledge
  – Exception does not include experiments « with » patented substance (=research tool), but provides mandatory license against compensation
  – Some countries allow for the patentability of research tools (utility of relaxed industrial criteria application)

• UK (House of Lords, 2009):
  – Generation of new knowledge must be preponderant purpose
  – Additional commercial purpose is fine
Implementation of experimental use exception

• No WTO jurisprudence on experimental use exception

• Key objective of exception: promote technological progress → the exception depending on the case could cover commercial aims, but arguably to justify use of patented product/process to develop different, technologically more advanced product.

• This is a common practice in developing countries Argentina, Brasil, India, China, etc.
Early working exception

Context:

• Part of the **regulated products sanitary approval or marketing approval**

• It is linked to the request by generic producer for marketing approval of drug including a substance patented by third party

• Generic producer needs to use patented material submit his request (bioequivance requirements)

• Otherwise request can only be processed after patent expiry → considerable delay of generic competition → need for an exception
Scope of early working exception

- WTO Panel in *Canada* – *Patent Protection of Pharmaceutical Products*
- Generic producer seeking marketing approval may use & produce patented product for the **sole purpose of obtaining approval**
- No commercial use of final product
- No unlimited stock of generic copies to be sold immediately after patent expiry
Implementation of early working exception

• For marketing approval purposes only

• No obligation to limit exception to approval requests made for domestic market (entire world or region: Canada’s law)

• No obligation to limit exception to actual request. May also cover use of patented materials during pre-clinical trials phase, if reasonable prospect that a request will be submitted (US Supreme Court in *Merck v. Integra Lifesciences*)
Conclusion

- It is recommended to exclude research tools from patentability (statutory or patent examination practice)
- Experimental use exception may be applied to acts done primarily for research, but ultimate commercial goals/consequences should not be excluded
  - Developed /developing country practice, but no WTO jurisprudence
- Early working exception may be used to justify production of patented substance for sole purpose of marketing approvals (beyond domestic market; including pre-clinical trials)
  - Confirmed by WTO jurisprudence
- Implementation of express exceptions into domestic law is crucial to avoid legal battles
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