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
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 (bioequivalence 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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