TRIPS Post-Grant Flexibilities: Parallel Imports

Workshop on Flexibilities in International Intellectual Property Rules and Local Production of Pharmaceuticals for the Southern, Central and West African Region
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Right Holder

- Production/License for Production / Low price
- No Production/No License for Production / or High price

A → ? → B
Exhaustion and parallel importation

- No definition in TRIPS
- Pharmaceutical context: different prices for patented drugs in different areas of the world
- Parallel importers buy patented drugs in low-price country and import them into high-price country to offer at lower prices than local price set by patentee
- Parallel imports are patented products and not counterfeits
- These imports are done in parallel to official channels of distribution authorized by the patentee
Parallel imports: legal issues (1)

- Patent provides bundle of rights (Art 28 TRIPS)
  - Exclude others from *making* the product
  - Exclude others from *distributing* the product (i.e. using, offering for sale, selling, importing)
- Distribution rights in a particular product are exhausted upon first sale of that product
  - Rationale: first sale as sufficient reward for patentee
  - But production right is not affected
  - Non-sold items are not affected
Parallel imports: legal issues (2)

- **Example**: sale of 100 boxes of HIV drugs will exhaust the patentee’s right to control further distribution of the contents of these 100 boxes by third parties.
- Patentee maintains control over distribution of other copies of the drug until actually put on the market.
- After marketing, third parties may further distribute the purchased copies, but must not start producing the drugs themselves.
Parallel imports: legal issues (3)

- Basis for rights exhaustion: marketing of patented product by patentee or with his consent
- Policy issue: may marketing of drugs based on compulsory license be considered a ground for exhaustion?
- Risk of WTO dispute settlement proceedings
Parallel imports: legal issues (4)

- Exhaustion after marketing. What market?
  - Domestic market (national exhaustion)
  - Regional market (regional exhaustion)
  - International market (international exhaustion)
  - Regional & international: domestic right is exhausted by sale in foreign country
  - TRIPS leaves Members free to decide (Art 6)
Parallel importation regime in Sub-Saharan Africa

- In Sub-Saharan Africa out of 40 countries:
  - The situation is unclear in 10 countries (Angola, DRC, Lesotho, Liberia, Malawi, Swaziland, Zambia),
  - six countries have clear provisions permitting international exhaustion (Ghana, Namibia, South Africa, Zimbabwe)
- OAPI countries (16) have a regional exhaustion regime;
- 10 other countries seem to provide for a national exhaustion regime (Botswana, Madagascar, Mozambique, Nigeria (draft bill provides for international regime) (UNDP, 2007)
Parallel imports: policy issues (1)

- International & regional exhaustion may promote supply of low-priced drugs in DCs
  - Example: HIV drugs sold in India at low prices may be imported in Ethiopia if international exhaustion is admitted

- Pharmaceutical firms in OECD need to be assured there will be no importation of low-priced drugs destined for DC markets
  - Example: HIV drugs sold in India at low prices are imported into Switzerland to undercut local prices
Parallel imports: policy issues (2)

• UK Commission on IPRs in its 2002 Report:
  • Developing countries seeking access to medicines should aim to facilitate parallel imports in their legislation
  • Developed countries should maintain & strengthen prevention of imports of low-priced drugs from developing countries
Parallel imports: beyond patents (1)

- Countries seeking to promote access to medicines need to look beyond patents: trademarks may play important role.
  - Example: country A authorizes parallel imports of patented drugs (through regional or international exhaustion); but provides national exhaustion of trademarks → to the extent that the patented drug is also protected by a trademark, importations may be blocked by the trademark holder (as distribution rights under trademark can only be exhausted by sale on domestic territory). To avoid this, parallel importer may create own brand, but needs consumer awareness & support.
Parallel imports: beyond patents (2)

• Even where parallel imports are authorized, patent holder may seek to prevent them through contractual obligations
  • Example: patent holder A authorizes his distributor B to sell the patented product only in B’s home country and not to sell the product to parallel trader C. C however could still seek to purchase the product from other sources and then engage in parallel trade.

• Such contractual limitations expressly referred to in free trade agreements
  • Examples: FTAs USA-Australia; USA-Morocco
Parallel imports: beyond patents (3)

• Even where parallel imports are authorized, the importer in order to market the product will still need the DRA’s marketing approval in the importing country.

• As parallel imports concern patented products (and not generics), marketing approval will normally have been secured already by the patent holder.
Parallel imports: conclusions

- Parallel imports may provide important sources of cheap drugs or ingredients needed for local production
- TRIPS leaves Members free to admit parallel imports
- Developing countries should consider concept of regional or international patent & trademark exhaustion
- It is controversial to base parallel imports/exhaustion on a (foreign) compulsory license
- Parallel imports are not counterfeits
Thank you for your attention

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