Price Differentiation in Pharma and the Conundrum of Exhaustion Principles

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Requirements for availability of Pharmaceuticals - I

- Creation of new, effective pharmaceuticals
  - R&D by researching pharma companies pre-condition
    - investment cost high, sometimes several 100 Mio. USD from detection of molecule/entity to NDA approval
    - expected Return Over Investment (ROI) driving force for R&D

Requirements for availability of Pharmaceuticals - II

- Distribution/sale of new, effective pharmaceuticals
  - high prices necessary at least in certain high-price countries
  - low prices necessary in low-price (less/least developed) countries
    - Price differentiation between high-price and low-price countries a “must”

How to achieve price differentiation

- Outside the European Union (EU)
  - Patent System with national/regional exhaustion
- Inside the EU
  - Patent System of no use, because of EU-wide “regional” exhaustion
  - Sales restrictions (“quota system”) a solution?
  - The problems with Art. 82 EC (Syfait I/Syfait II)

National vs. International Exhaustion of Patents – a matter of principle

- Pro international exhaustion:
  - Remuneration/Award for inventors only justified once
- Pro national exhaustion: national/territorial character of patents – remuneration/award per patent/country justified

Licensing under specific conditions a solution for Pharma?

- Royalty schemes could be structured in such a manner that exportation from license territory unattractive
  - Increasing, volume-dependent running royalty rates instead of usually, otherwise, used decreasing royalty scheme
- Direct export restrictions in license agreements

Sales/Export quota system, in case of International Exhaustion of patents a solution for Pharma?

- Syfait I/Syfait II scenario world-wide applicable?
- Extraterritorial application of competition/antitrust laws would cause problems
  - Nevertheless, in case of acceptance of unmodified international exhaustion possibly best way to achieve price differentiation in pharma

„Modified“ International Exhaustion a solution for Pharma?

- Even for pharma, “modified” international exhaustion could in principle be accepted
  - In pharma, special conditions should justify use of parallel patents for restricting re-importation and parallel imports, respectively
  - Prevention of parallel importation by patents could/would be permitted if sales price in less/least developed country/countries less than
    - 10% of average sales price in all (or selected) OECD countries (or country of origin), prevention of parallel imports by patent(s) permitted or
    - average sales price in all (or selected) OECD countries (or country of origin), multiplied by

      GDP-per-capita in country of sale

      GDP-per-capita in OECD-country/countries