What Future for the European Patent System?

Diversity in Innovation

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Diversity?

- **Art. 27 TRIPS (1994):**

  "Patents shall be available and patent rights enjoyable without discrimination as to the … field of technology"

- **Intention:**
  - to guarantee protection for a variety of subject matters previously not protected by patent rights in many countries
  - does not prohibit bona fide exemptions to deal with problems that may exist only in certain product areas

  (Report of WTO Dispute Settlement Panel, Canada-Patent Protection of Pharmaceutical Products, 2000)

- **Analyses:**

  See Graham B. Dinwood/Rochelle C. Dreyfuss, "Diversifying without discrimination: Complying with the mandates of the TRIPS Agreement", 13 MICHIGAN TELECOMMUNICATIONS AND TECHNOLOGY LAW REVIEW 445 (2007)

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Remedy 1: "Inventive Step" (1)

- **Requirements** (international/national legislation):
  - **Novelty**
    - "absolute" (worldwide state of the art)?
    - "relative" (national state state of the art)?
  - **"Non obviousness"**
    - abstract, open term
    - leaves room for (certain) differentiation

- **Examples:**
  - Mechanical inventions/combination with electronic control
    (US Supreme Court, *KSR Int. Co. v. Teleflex Inc. et al*, 550 U.S. 1 (2007))
  - Pharmaceutical Inventions
    "Clivec"-Case (Novartis), India
    ("Clivec" = trade name by Novartis; "Imatinib" = substance, formerly known)

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Remedy 1: "Inventive Step" (2)

- **Requirements** (international/national legislation):
- **Examples:**
  - Mechanical inventions/combination with electronic control
    (US Supreme Court, *KSR Int. Co. v. Teleflex Inc. et al*, 550 U.S. 1 (2007))
  - Pharmaceutical Inventions

    Patent of Novartis…

    - … describes
      - **transformation** of "Imatinib" from **α-crystalline** formulation
      - (discovered in early 1990; not reabsorbable)
      - into **β-crystalline** formulation (= reabsorbable)
    - … consist (basically) of claims for
      - **substance** as such (in β-crystalline formulation)
      - **combination** of substance and pharmaceutical carrier
      - **procedure** to get the β-crystalline formulation

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Remedy 1: "Inventive Step" (3)

- **Requirements** (international/national legislation):
- **Examples:**
  - Mechanical inventions/combination with electronic control
    (US Supreme Court, *KSR Int. Co. v. Teleflex Inc. et al*, 550 U.S. 1 (2007))
  - Pharmaceutical Inventions

    Patent of Novartis…

    - … describes …
    - … consists …
    - … claims procedure based on
      - **mixture** ("Imatinib" α-crystalline form + solvent + water)
      - **heating** of mixture (20-50 °C; 25 °C →some initial β-crystalline forms)
      - possibility of adding β-crystalline as seed crystals
      - **intermediate** formulations (δ- and ε-crystalline, for purification) to be achieved with similar procedure, but different solvents
        - α → δ = Aceton and Methanol
        - α → ε = Ethylacetat and Ethanol

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Remedy 1: "Inventive Step" (4)

- **Requirements** (international/national legislation):
- **Examples:**
  - Mechanical inventions/combination with electronic control
    (US Supreme Court, *KSR Int. Co. v. Teleflex Inc. et al*, 550 U.S. 1 (2007))
  - Pharmaceutical Inventions

    Patent of Novartis…

    - … describes …
    - … consists …
    - … claims …
    - … has been **granted in 36 Countries – but not in India**:
      - Sec. 3d Indian Patent Act: Requirement of "…enhancement of the know efficacy"
      - Indian Pat. (GB2398565, granted 2006) = "Process of preparing Imatinib and Imatinib prepared thereby"

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Remedy 2: Scope of Protection (1)

- **Example**: **Substances** (chemical products)
  - purpose-bound protection?
  - full product protection?
    - USA: always
    - GB: until 1919, from 1949
    - France: 1959 (special legislation); 1968 (patent law)
    - Germany: 1968
    - EPO: 1973 (beginning)
- **Recent "layers" of full product protection:**
  - **biotechnology**
  - **nanotechnology**
- **Problem: Scope of protection covers …**
  - … not only purposes (consciously) invented by inventor
  - … but every – unknown – purpose/effect of product

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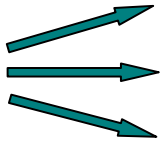
Remedy 2: Scope of Protection (2)

- **Remedy:**

  Inventions with **different** economic effects …

  - **mechanical**
  - **substances**

  chemical products
  biotechnological material
  nanotechnological building blocks

  … require **different legislative solutions**

→ **Full product protection = historical mistake?**

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Remedy 2: Scope of Protection (3)

- **Worsening of the situation:**
  - **"Swiss-type claims"**
    (= newly discovered effects of pharmaceutical substance)
    = wrong form of "differentiation"
  - Protection of **specific purpose** (effect) of substance
    - cannot be deemed being an "exception" …
      (effect = extension of term for full product protection!)
    - … but must be the rule:
      - **only** the **specific** – disclosed (!) – **purpose** of a substance may be protected by a specific patent
      - **newly** found purposes may be subject of **new patents**

    → incentive for third parties to develop new fields

    → bans risk of monopolising "essential facilities" (e.g. nanotechnology)

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Remedy 3: Abolish „One size fits all“

- **Patent law today knows …**
  - … exclusions of protection
    → (partially) aiming at different approaches of protection
    (e.g. plant varieties protection)
  - … extensions of protection
    → aiming on differentiation of amortisation possibilities
    (e.g. supplementary protection certificate)

- **Why not extend that approach?**

  e.g. with regard to
  - computer programs
  - “living material” (biotechnology)
  - naturally existing building blocks (e.g. nanotechnology)
  - …

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Remedy 4: Exceptions and Limitation (1)

- **Discrepancy between**
  - existing exceptions (established mandatory licences)
  - reality (practical use of legal instruments)
- **Discrepancy between**
  - patent law = very limited scope of exceptions, e.g.
    - health care
    - public security
  - copyright law = accepted means of balancing interests
- **Underdevelopment of legal instrument:**
  - mandatory licensing (negotiation/litigation required)
  - only few "free" limitations (e.g. research exemption)
  - no "legal licences" (remunerations system for use acts)

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Remedy 4: Exceptions and Limitation (2)

- **Advantage of exceptions/limitations:**
  - gradually possible balancing of diverging interests
  - possible differentiations of specific fields of technology
  - single market participant may benefit (←→ antitrust law)
- **Problems of exceptions/limitations:**
  - unclear legal certainty (lack of experience)?
  - too high transaction cost?
  - **institutional problems → European Patent System!**

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Remedy 4: Exceptions and Limitation (3)

- **Problems of Europe Patent System:**
  - national legislations applicable
  - lack of harmonisation (EPC; EU)
  - national litigation inevitable =
    - huge number of legal actions required to "cover" Europe
    - possibly diverging jurisprudence

- **Remedies for European Patent System:**
  - unitary legal system (Community Patent)
  - existing European Patent System, but
    - harmonization of applicable (national) law
    - unitary litigation system = "one decision" (→ EPLA??)

→ in any case: **expansion of existing legal framework!**

Art. 30 TRIPS:
"… taking account of the legitimate interests of third parties"

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Remedy 5: Competition Law

- **Competition Law ("antitrust law") is**
  - principally applicable on IP matters
  - but practically insufficient
    - only "great" cases
    - particular requirements
    - transaction costs

- **"Special" (= IP-related) Competition Law**
  - considering particularities of different "technology markets" (exists with regard to IP contracts – but not IP "misuse")
  - differentiating effects in different fields of technology, notably
    - substitutable technologies
    - non-substitutable technologies ("essential facilities")
  - regarding procedural particularities (e.g. fast, low-cost trials)

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Remedy 6: Solve "European Problems"

- **An internal market requires unitary legal systems …**
  … but unitary legal systems may be achieved differently
- **Conflicts of competence EU – EPO should be stopped:**
  - disputes of competence impair European economy
  - coexistence of current Patent System and Community Patent
  - need of action is not uniform, but differentiations are possible
- **Different industries are differently affected by**
  - internal market
  - international competition
  - …

→ **Different approaches for different fields of technology?**
(e.g. starting Community Patent with regard to Pharmacy only??)

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Conclusions

- **A number of remedies exist.**
- **They (mostly) do not conflict with international law…**
  (but might require clarification, e.g. differentiations with regard to different fields of technology)
- **… but national/European legislation might be adopted**
  (e.g. renunciation of full product protection)
- **Some remedies require some imagination …**
- **… but ultimately just reflect practical experiences**
- **Significant responsibility for jurisprudence, e.g.**
  - protection requirements (“inventive step”)
  - creation/clarification of limitations/exceptions
  - appropriate application of competition law
- **Demarcation disputes in Europe must end!**

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