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TRIPS Pre-Grant Flexibilities: Patentability Criteria

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Overview of Presentation

- Rights under a granted patent
- Patentability criteria under TRIPS
  - Novelty
  - Inventive step
  - Industrial applicability
- Ever-greening of patents
  - New uses of known products
  - Derivatives of known products

TRIPS Article 27.1 on patentability criteria

- Subject matter that
  - Constitutes an invention (natural substances!) and
  - is not excluded from patentability (methods of medical treatment)

- Such patentable subject matter still needs to meet three criteria:
  - Novelty
  - Inventive step (non-obviousness)
  - Industrial applicability (utility)

Patents: scope

- A product (e.g. pharmaceutical)
- A way of making the product
- A way of using the product
- Some combination of the above
- TRIPS Article 28.1:
  - Product patents
  - Process patents

Product patents

- 28.1 (a) TRIPS: Right to prevent third parties not having the owner's consent from the acts of
  - making,
  - using,
  - offering for sale,
  - selling, or
  - importing for these purposes that product (subject to exhaustion of patent rights)

Process patents

- 28.1 (b) TRIPS: Right to prevent third parties not having the owner's consent from
  - the act of using the ***process***, and
  - from the acts of:
    - using,
    - offering for sale,
    - selling, or
    - importing for these purposes at least the ***product obtained directly by that process***.

Difference product – process patents (1)

- Product patents are broader: if A obtains a patent on a pharmaceutical substance, competitor B may not make/copy this substance: no reverse engineering
- If A obtains a process patent, B may not use
  - this particular process (**but other processes**)
  - the final product ***as obtained by that process***
  - but B may use **another process to make identical product**→reverse engineering, Indian example

Difference product – process patents (2)

- In sum, product patent claims cover
  - All possible methods of ***making*** the product
  - All possible methods of ***using*** the product
  - Even if these methods of using & making were unknown to patent holder when filing application
  - Countries may adopt narrower approach: product patent covers only uses that are indicated or implied in the claims (« use-bound claims »)

Novelty (1)

- Policy considerations: strict novelty standard will restrict exclusive rights to truly new products & preserve broader public domain for follow-on innovation & research
- No TRIPS definition of novelty → Members free to construe strict or lax novelty standards

Novelty (2)

- In general: anything not available to the public prior to the date of patent application
- Strict novelty standard:
  - Written and oral disclosures of the invention anywhere in the world
  - Disclosure in a single document or several publications
  - No requirement of express teaching → implicit
  - Information from other patent applications
  - Only theoretical possibilty of access is sufficient

Novelty: example

- Big pharma company A obtains patent for HIV drug in OECD countries, but chooses not to apply for patent in Senegal. Patented drug is not available on domestic market.
- 5 years later, A changes its strategy and applies for patent in Senegal.
- In case of national novelty standard: drug is new (has never been available to Senegalese public before).
- In case of worldwide novelty: drug lacks novelty: has been available to the public in other countries for 5 years $\rightarrow$ patent may be rejected.

Inventive step (1)

- No TRIPS definition of inventive step → Members free to construe strict or lax inventive step standards
- In general: anything that would not have been obvious to a person skilled in the art on the date of the patent application, having regard to prior art (=existing knowledge)

Inventive step (2)

- Assessment of non-obviousness may be based on average skills in high tech countries → increases likelihood of obviousness
- No need for single & precise prior art teachings (US Supreme Court, *KSR*)
  - Look at typical level of creativity & insight of average person skilled in the art
  - Look at design needs & market pressure

Inventive step: policy considerations

- Inventive step standard defines the line between free competition and legal incentives to innovate
- How & where to draw that line depends on a country's choice to what extent its domestic industry should remain free to reverse engineer
- In principle, countries with modest inventive capacity will benefit more from high standards of inventive step (more reverse engineering & competition)

Industrial application (1)

- The third TRIPS requirement for patentability (after novelty & inventive step)
- Rationale: to promote technical & practical solutions, but no monopolization of theoretical knowledge needed for follow-on innovation
  - Example: general theories used in chemistry
- No TRIPS definition → Members free to construe strict or lax standards

Industrial application (2)

- In general: any invention that may be manufactured or used in any commercial activity→ need for an industrial product
- Purely experimental inventions & ***biotechnological research tools*** lack industrial application (EPO) and «substantial utility» (USPTO)→ remain available for generic producers
- Need to identify practical way of using research tool in at least one field of industry (EPO, 2005)

Industrial application: example

- Researcher A seeks a patent on an expressed sequence tag (EST) (=part of a gene). Disclosed use: Isolation of protein-encoded genes "**to perform further research"**
- The patent office considers the EST as new & non-obvious (isolation from natural environment). But need to disclose one particular function; general reference to further research not sufficient (US Federal Circuit, *In re Fisher*, 2005)
- A patent on the EST would block an important tool for other researchers → potential threat to effective biomedical reseach & progress
- If industrially applicable → need to find way to avoid blocking effect on research (research exemption; license of right)

Evergreening of drug patents

- Patentability criteria play important role in addressing evergreening attempts
- Evergreening takes place
  - Either through patenting of new uses of known products (=different uses of one identical product)
  - Or through patenting of slight structural changes of the original substance: product derivatives (=no product identity)

New uses of known products: implications for generic producers

- New uses may be patentable
  - As processes (method of use patents) → only the specific new use, but not other uses
    - Generic producers may not produce & sell drug for HIV treatment, but for cancer treatment → difficult to enforce
  - As products → substance and any of its use
    - Generic producers may no longer produce & sell drug at all or reverse engineer

New uses of known products: legal issues (1)

- Last presentation → may be considered non-patentable subject matter if *natural* substances or excluded as methods of medical treatment, 27.3(a) TRIPS
- But *chemical* substances are patentable subject matter. *Methods* of treatment exclusion does not prevent *product* patents
- Thus, the new use issue comes up again in the context of patentabilty criteria

New uses of known products: legal issues (2)

- ***Product*** patent protection? May be refused for lack of novelty: product as such has been available to the public, irrespective of discovery of new use
- ***Process*** patent protection?
  - New use may satisfy novelty requirement
  - But may be obvious if new use is predictable for person skilled in the art (developed country standard)

New uses of known products: legal issues (3)

- Result: a country's patent law or patent examination guidelines may
  - Reject ***product*** patents for new uses
  - The treatment of new uses as ***process*** patents is case-specific and protection cannot be generally excluded
  - Alternative means of protection: « use & pay » for incremental innovation (e.g. traditional medicines applications)

Product derivatives patents: policy issues (1)

- Do ***structurally similar*** compounds merit patent protection in case they show ***superior therapeutic properties***?
  - Example: prior art compound was inactive, but slight structural modifications lead to anti-inflammatory properties

Product derivatives patents: policy issues (2)

- How to address incremental innovation (i.e. slight structural changes to existing products)?
- Incremental innovation is much more feasible for local firms in DCs than truly non-obvious breakthrough inventions
- As a result, should a DC lower its standards of novelty & inventive step to promote domestic innovators?

Product derivatives patents: policy issues (3)

- Local innovators may benefit from OECD lower patent standards, irrespective of domestic standards (independence/territoriality of patents)
- DCs companies often lack critical amount of technological capacity → depend on follow-on research & broad public domain
- Patents on small changes may easily block follow-on innovation

Product derivatives patents: legal issues (1)

- In theory: patents may be granted separately on the original substance and each of its variations
- In practice: difficult for judge to understand exact scope of claimed patent → potential of abuse
- Need to limit patents on trivial changes: strict patentability criteria

Product derivatives patents: legal issues (2)

- Lack of ***novelty***: similar to known product (concept of implicit teaching = strict novelty standard)
- Slight structural modifications may set *prima facie* case of ***obviousness***. Patent applicant may ***rebut*** by showing unexpected or improved properties (US law) or significantly enhanced efficacy (Indian law)
- If product patent is rejected, still possibiltity of process (method-of-use) patent for new & non-obvious use of product derivative
- If product patent is granted, need to prevent blocking of downstream product improvement → CL Art 31 (l) TRIPS

Alternative ways to protect derivatives

- Utility models for small inventions (Australia, Germany, Italy, Japan)
- « Use & pay »: no exclusive rights, but right to compensation if derivative is used by third parties for improvements → avoids blocking effects

Patentability Criteria: Conclusions

- TRIPS does not define novelty, inventive step & industrial applicability
- Strict standards will keep broad public domain for follow-on innovation
- Product patents for new uses: lack of novelty
- Product patents for derivatives: lack of novelty or inventive step, unless showing of improved therapeutic effect or unexpected properties
- Incremental innovation in DCs may be promoted by alternative means of protection (UMs; compensation)

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