

Patentability Criteria: Setting the Standards under TRIPS

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INITIATIVE FOR MEDICINES ACCESS & KNOWLEDGE

Background to Patentability Criteria

- Novel (New)
- Inventive Step (non-obvious); and
- Industrial Application (Utility/Use)
- Sufficient disclosure of invention



TRIPS Requirements

Article 27(1):

....patents shall be available for **any** inventions, whether **products** or **processes**, in all fields of technology, provided that they are **new**, involve an **inventive step** and are capable of **industrial application**.

...patent rights enjoyable without **discrimination** as to the place of invention, the **field of technology** and whether products are imported or locally produced.



TRIPS Requirements (cont'd)

Article 27(2):

Members **may exclude** from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.



TRIPS Requirements (cont'd)

Article 27(3) - Members **may also** exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.



TRIPS Requirements (cont'd)

Article 29:

Members shall require that an applicant for a patent shall disclose the invention in a manner **sufficiently clear** and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the **best mode** for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.



Doha Declaration

Paragraph 4:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to **protect public health**. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the **Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health** and, in particular, to promote access to medicines for all.

WT/MIN(01)/DEC/2



Standards of novelty

- Form of disclosure/state of art - prior publications/unpublished prior patent applications, existing common knowledge/ prior use.
- Relative and absolute novelty (or mixed novelty e.g 35 USC 101).
- Disclosure describing exactly the invention claimed
Mosaicing of prior disclosures.
- Inherent anticipation.
- Selection inventions - special advantages?



Inventive Step (Non-obviousness)

“It was never the object of the [patent] laws to grant a monopoly for every trifling device, every shadow of a shade, of an idea, which would naturally and spontaneously occur to any skilled mechanic or operator in the ordinary progress of manufactures”

Justice Bradley - Atlantic Works v Brady U.S (17 Otto) 292, 1883

“for a new device to be patentable it must reveal the flash of creative genius”

Justice Douglas - Cuno Engineering Corp, 314 U.S 84, 51 U.S.P.Q, 1, 1941



Inventive Step (Non-obviousness) - cont'd

- Disclosure - state of the art to include unpublished prior patent applications, common knowledge, publications.
- Obvious to person skilled in the art - hypothetical addressee unimaginative or one with specialist knowledge?



Inventive Step (Non-obviousness) - cont'd

- Reasonable expectation of success/obvious to try?
- Surprising/unexpected effect - but was it obvious?
- Commercial success/economic significance?



Industrial application/Utility

A stricter standard of 'usefulness' - *Re Brana 51 F.3d 1560, Fed. Cir. 1995* - actual therapeutic value in humans?



Sufficiency of disclosure

- Apply the standard according to local skilled person.
- Can be used to block applications disclosing large number of compounds 'markush claims' - e.g Oseltamivir.



Setting stricter standards

- WTO member countries interpret the term 'invention' differently. E.g 35 U.S.C s100 - invention means invention/discovery, new uses.
- India s3d - new forms of known substances are the same substance unless significant difference in properties with regard to efficacy.
- India s3(e) mere admixtures that only increase aggregation of properties but no synergy between the two ingredients (useful for rejecting combination patent applications/formulation patents).

