

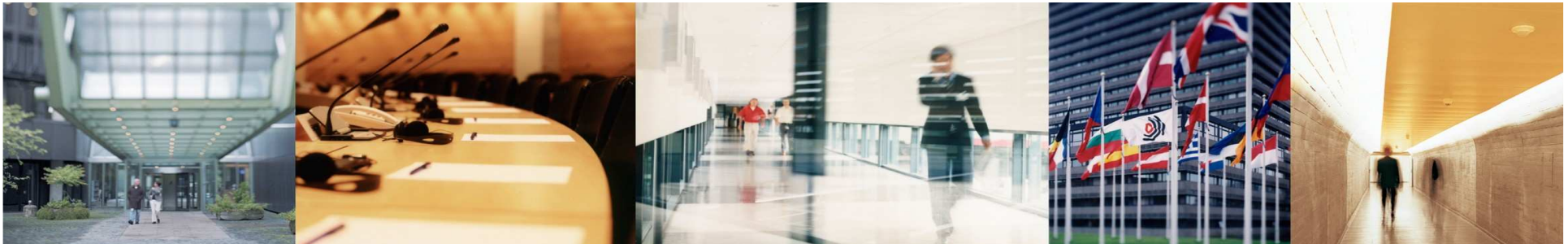


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# Protection of Biotechnological Inventions via the EPO

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# Patentability Requirements I

- Article 52 EPC : Patentable inventions
  - (1) European patents shall be granted for any inventions
    - which are susceptible of industrial application,
    - which are new and
    - which involve an inventive step.

# Patentability Requirements II

- Industrial Applicability : Art. 57 EPC
  - A direct technical result that
    - may clearly be applied in an industrial activity [T338/00]
    - can be derived from the description (Rule 27(1) (f) EPC)
  - For a protein or a DNA found in nature, a practical application needs to be envisaged [T870/04]
  - Elucidation of a function may be enough [T0898/05] but must be based on reliable methods [T0641/05]

# Patentability Requirements III

- Novelty : Art. 54 EPC
  - No novelty if subject-matter is derivable directly and unambiguously from a prior art document
  - A functional definition may hide a lack of novelty and thus not be the technical feature establishing novelty

# Patentability Requirements IV

- Inventive step : Art. 56 EPC
  - A link between a technical feature and a technical effect, often a claimed function, is required
  - The technical effect should be achievable over the whole claimed area [T939/92, T893/02] to solve the problem
  - Post-published evidence may not be considered [T1329/04] without evidence in the application

# Patentability Requirements V

- Sufficiency of disclosure : Art. 83 EPC
  - Product definition by structural/functional features
  - Reference to a deposited biological material : Rule 28 EPC
  - At the effective date [T609/02]

# Medical use claims I

- EPC2000, Art. 52 on Patentable Inventions :
  - (1) European patents shall be granted for any inventions, *in all fields of technology*, provided that they are new, involved an inventive step and are susceptible of industrial application.
- Biotechnology is the only technical field with its own regulation under the EPC :
  - Article 53(b) EPC : EU-directive 98/44/EC , Rule 23b-e EPC
  - Rule 27a, rule 28, rule 28a EPC
  - Article 52(4) : medical/diagnostic methods
  - Article 53(a) : "ordre public" and morality
  - Article 54(5) : first/second medical use of known compounds

## -Second- medical use claims II

- Formulation under EPC2000 :
  - "Compound x for use in the treatment of disease Y"
    - for applications
      - filed on or after 13 December 2007
      - pending at that time
- If a novel technical feature, related to :
  - a disease
  - a group of subjects to be treated
  - a mode of administration
  - a prescribed administration regimen, dosage
    - is clearly shown by adequate experiments to be associated with a technical effect***

# Medical use claims III

- Is a protection foreseen ?
  - for clinical research
  - for personalized therapy with a defined group of patients
  - for a mechanism of action or an effect only : No
    - but if linked with a disease (Article 84 EPC) : Yes

# Monoclonal Antibodies I

- Antibodies
  - are defined by a combination of structural ("antibody") and functional (binding specificity) features but their level of precision depends on the prior art....
- Structural feature
  - definition based on the CDRs sequence may not be acceptable since any framework regions associated with specific CDRs do not allow the preparation of antibodies having the wished properties

# Monoclonal Antibodies II

- Functional features
  - generalization based on the binding specificity : "***or binding fragment thereof***" if the Fc part of the antibody is not involved in the technical effect supporting an inventive step. The Fc domain is essential in ADCC and complement binding
  - generalization based on the particular function leading to an inventive step : "***induces apoptosis***" if clear and testable [T1300/05] and not disguising a lack of novelty [T735/00]

## Mastering the Workload

- Annually the Biotech departments at the EPO
  - receive about 8400 new applications for searching
  - produce about 8000-9000 searches
  
  - receive about 5500-6000 requests for examination
  - produce about 6000-6500 final actions in examination
    - Of which about 3300 grants
  
  - publish about 2800-3000 grants
  - produce 170-200 oppositions