Patentability in Biotechnology

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Introduction to the European Patent Organisation.

European Patent Organisation

European Patent Office

Administrative Council

The executive body

The legislative body

The Administrative Council consists of delegates from the 38 member states

(the 27 EU member states plus Albania, Croatia, the former Yugoslav Republic of Macedonia, Iceland, Liechtenstein, Monaco, Norway, San Marino, Serbia, Switzerland and Turkey (01.10.2010)).

The European Patent Organisation is a financially independent self-supporting intergovernmental organisation, and NOT an EU organisation.
What is a patent?

- A patent is a set of exclusive rights granted by a state to a patentee for a fixed period of time in exchange for a disclosure of an invention.

- A patent is a legal and economical instrument.

- A patent confers the right to exclude others from the economical utilisation of the invention.

- A patent does not confer the right to practice or use the invention.
  - National Law.
  - Freedom to operate (overlapping earlier patent rights).
The life of a European patent application
Article 52(1) EPC - Patentable Inventions

European patents shall be granted for any inventions, in all fields of technology, provided that:
- they are new,
- involve an inventive step and
- are susceptible of industrial application.
Patentability requirements

• **Invention (versus Discovery)**
  - An invention must have a *technical character*

• **Main legal requirements:**
  - **Novelty** (Art. 54 EPC)
  - **Inventive Step** (Art. 56 EPC)
  - **Industrial Application** (Art. 57 EPC)
  - **Sufficiency of disclosure** (Art. 83 EPC)
  - **Unitary** (Art. 82 EPC)
  - **Clarity** (Art. 84 EPC)
  - **Morality** (Art. 53(a) EPC)
Is everything patentable?

NO

- Non-Inventions (Art. 52(2) EPC)
- Exceptions to patentability (Art. 53, Rules 28 & 29 EPC)
Non-inventions (Art. 52(2) EPC)

The following, in particular, shall not be regarded as inventions:

- discoveries, scientific theories and mathematical methods;
- aesthetic creations schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- presentations of information
  (eg. Protein structures/coordinates based on NMR, a computer disk comprising information).
Discovery or Invention? **Penicillin**

- A mere finding of something already existing in nature is a **Discovery**: Contamination with mold kills bacteria.

- If a technical character is associated to this discovery, then, this can be regarded as an **Invention** (isolated fungus, means for its culturing, isolated antibiotic agent).

- An invention is always **technical** in nature, consisting of a reproducible technical teaching (isolation, purification, characterization, preparation, use).

- A discovery is **cognitive** in nature, e.g. finding a plant, finding a mineral.
Exceptions to patentability (Art. 53(a), Rule 28 EPC)

European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to „ordre public“ or morality, ...

- processes for cloning human beings,
- processes for modifying the germ line genetic identity of human beings,
- uses of human embryos for industrial or commercial purposes,
- processes for modifying the genetic identity of animals, which are likely to cause suffering without any substantial medical benefit to man or animal and also animals resulting from such processes.

Examples:

Viruses

Landmines
The life of a European patent application

..., such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states.
(Art. 53(a) EPC; 2. Sentence)

A European patent does not confer the right to perform or use the invention, this is regulated by national law.
Patentable biotechnological inventions (Rule 27 EPC)

• Polypeptides and enzymes
• Protein crystals
• Agonists or Antagonists
• Isolated DNA and RNA molecules (e.g. siRNA)
• Genes
• Plasmids and vectors
• Monoclonal antibodies and hybridomas
• Microorganisms (e.g. bacteria, viruses and phages) or cells which are of non-human embryonic origin
• Plants and non-human animals
• Microarrays, diagnostic kits (e.g. ELISA)

• As well as methods for the preparation of these products and their use
Novelty (Art. 54 EPC)

An invention shall be considered to be new if it does not form part of the state of the art.
State of the Art

Everything made available to the public by means of ...

...before the filing date of the application

written description

oral description

by use

or in any other way
Can I discuss the details of my invention with a potential investor before filing a patent application?

- Any invention which is made public (by oral or written disclosure) before an application is filed would be considered as known and not novel!

- It is important to file a patent before publicly disclosing the details of an invention to anyone, anywhere, anytime.

- Think about drawing up a "declaration of secrecy", do not allow photographs to be taken!

- Talk to your patent lawyer before talking with a potential licensee, or showing a guest around in your lab.
The EPC is a First-to-file system

In a first to file system, the right to the grant of a patent for a given invention lies with the first person to file a patent application for protection of that invention, regardless of the date of the actual invention.

In contrast, in the United States a first-to-invent system is applied.
Inventive step (Art. 56 EPC)

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

A practical and objective approach is needed to assess obviousness.

The problem-solution approach
Inventive Step: Problem-Solution Approach

Five steps

1. determine the closest prior art
   - the CPA must deal with the same general problem

2. determine the distinguishing features (difference(s))

3. determine the technical effects obtained by these features (difference(s))

4. define the technical problem to be solved on the basis of the identified difference(s)

5. answer the question:
   starting from the closest prior art and facing this technical problem, would a person skilled in the art arrive at the claimed solution?
Is it obvious?

• avoid *ex post facto* analysis
• could - would
• positive attitude in trying ... obvious to try?
• incentive in the prior art to ... ?
• reasonable *expectation of success* ... ?

• surprising / unexpected effect?
• technical effect provided by the extra feature?
• technical effect present *over the whole claimed scope*?
• was the problem solved over the whole claimed scope?
Example: EP0973534

- Plant extracts having appetite suppressing activity

1. Use, in the manufacture of a medicament having appetite-suppressant activity for treating, preventing or combating obesity of a human or animal, of an extract from a plant of the genus Trichocauleon or the genus Hoodia, which extract contains an effective amount of an appetite-suppressant steroidal glycoside from said plant, wherein the steroidal glycoside has the formula

Traditional knowledge: "eating the fibrous, water rich stems ... saved further suffering from the pangs of hunger ..."

The board of appeal ruled that this knowledge did not indicate that extracts from this plant would have appetite suppressing activity
Industrial Application (Art. 57 EPC)

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.
General remarks with regard to Art. 56/57 EPC

• There has to be a non-obvious, unexpected or surprising technical effect of the claimed DNA sequence/protein/compound, thereby solving a technical problem, suggesting a practical application.

• The function of a DNA sequence/protein/compound has to be specific, "reasonably credible", and present over the whole claimed scope, whatever method is used for its assessment.

• A mere DNA or amino acid sequence without a specific function is not inventive because it does not solve a specific technical problem and, consequently, it is not industrially applicable.
Clarity (Art. 84, Rule 43 EPC).

- The claims shall be clear and concise...

- The claims shall define the matter for which protection is sought in terms of technical features
Clarity (Art 84 EPC) – cont’d

→ expressions such as: analogues, variants, derivatives, fragments, prodrugs, etc. are generally not acceptable under Art. 84 EPC

→ “homology” and “similarity” are ambiguous terms, although generally accepted. Describe the meaning of these terms in the specification

→ use "identity" and length over which identity is calculated

→ If hybridizing sequences are claimed, indicate:
  hybridization conditions in the description and limit the hybridizing sequence by its function in the claim

→ Functional descriptions of features should be avoided as much as possible
A polypeptide of the formula:

\[ R^N - R^1 X^1 R^2 X^2 R^3 X^3 R^4 X^4 R^5 X^5 R^6 X^6 R^7 X^7 X^8 R^9 R^{10} R^{11} X^{11} - R^C \]

wherein,

- \( R^N \) is a group of about 1 to 552 independently selected amino acids;
- \( R^1 \) is a group of 3 independently selected amino acids;
- \( X^1 \) is an amino acid with a charged or uncharged R group;
- \( R^2 \) is a group of 7 independently selected amino acids;
- \( X^2 \) is an amino acid with a charged R group;
- \( R^3 \) is a group of 5 independently selected amino acids;
- \( X^3 \) is an amino acid with an apolar R group;
- \( R^4 \) is a group of 3 independently selected amino acids;
- \( X^4 \) is an amino acid with a charged R group;
- \( R^5 \) is a single independently selected amino acid;
- \( X^5 \) is an amino acid with an apolar R group;
- \( R^6 \) is a group of 15 independently selected amino acids;
- \( X^6 \) is an amino acid with a charged or uncharged R group;
- \( R^7 \) is a group of 2 independently selected amino acids;
- \( X^7 \) is an amino acid with a charged R group;
- \( X^8 \) is an amino acid with a charged R group;
- \( R^9 \) is a group of 2 independently selected amino acids;
- \( X^9 \) is an amino acid with a charged R group;
- \( R^{10} \) is a group of 3 independently selected amino acids;
- \( X^{10} \) is an amino acid with an uncharged R group;
- \( R^{11} \) is a group of 2 independently selected amino acids;
- \( X^{11} \) is an amino acid with an apolar R group; and
- \( R^C \) is a group of about 1 to 100 independently selected amino acids.

Example: broad is not necessarily unclear

Support ?
Problem solved ?
Technical effect ?
Conclusions

If biological molecules have been isolated or technically produced, they are patentable, provided that:

- The application assigns a specific and credible function
- They are neither known nor obvious
- They are clearly and unambiguously defined by technical features and
- The application sufficiently discloses how they can be obtained, and used
Methods for the treatment of a disease under EPC2000

• Art. 53 (c) EPC:
  European patents shall **not be granted** in respect of:
  Methods for treatment of the human or animal body by surgery or therapy or diagnostic methods practised on the human or animal body.

• But are patentable if formulated in the following manner:

  - "Compound X for use in a method for the treatment of a disease"
    (cf. Art. 54(4) EPC)
  - "Compound X for use in a method for the treatment of disease Y"
    (cf. Art. 54(5) EPC)
  - **Swiss-type claims are no longer allowable** for new patent applications
    (cf. G-2/08)
Thank you for your attention!

Questions?

The European Patent Organization
HTTP://WWW.EPO.ORG