Principles of EPO Patent Practice Biotech Inventions

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Current situation

Patent Law is governed by

national legislation (US, JP, DE, BE, NL ...)

regional legislation (EC, EPC, EA,...) or

international agreements (TRIPS, PCT ...)

Differences in Patent Law

- However, there are currently some important differences between the patent systems of different states, e.g. the territory of the contracting states of the EPC, US and JP with regard to both, the standards for Patentability and Granting Procedure.
- Harmonization is desired, e.g. via International Regulations such as TRIPS.

TRIPS Patentable Subject Matter

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**...

TRIPS Art. 27 continued

2. Members may **exclude** from patentability **inventions**, ...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 Art. 27 continued

3. Members may also exclude from patentability:

   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

TRIPS Art. 27 continued

(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.

EPC

- The European Patent Convention fulfills basically all requirements of the TRIPS agreement.
- But also the exclusions of Article 27 (3)

European Patent Convention and European Community

- Although a European patent is granted uniformly for all member states it can be treated differently after grant (different scope of protection, other understanding of novelty or inventive step in nullity suit etc.)
- Therefore, the EC decided to harmonize the scope of patents at least with regard to biotechnology, namely via the Directive 98/44 EC, the so-called Biotech Directive

EPC Granting Procedure

- The procedure comprises of two (sometimes three) phases:
- Phase 1:

  Filing the application, examination on filing and formalities examination, search, publication of application and search report

- Phase 2: Substantive examination (grant of patent or refusal of application)

The three criteria for patentability are:

- novelty
- inventive step
- industrial applicability

Further, the invention has to be reproducible.

- If a European patent is granted, competence is transferred to the designated contracting states, where it affords the same level of legal protection as a national patent.
- On average it takes 44 months to obtain a European patent.

- Phase 3: (in some cases) Opposition and Opposition Appeal
- Within nine months of the date of grant, any third party may file an opposition against a patent they believe does not comply with the substantive provisions of the EPC.

Patentable Matter under EPC Regulations

Article 52 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.

Article 52 (continued)

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

Article 52 (continued)

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

Article 52 (continued)

(3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

Article 52 (continued)

(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 53 Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the 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;

Article 53 (continued)

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

Rule 23c Patentable biotechnological inventions

Biotechnological inventions shall also be patentable if they concern:

(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

Rule 23c (continued)

(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

(c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

Rule 23d Exceptions to patentability

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;

Rule 23d (continued)

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Rule 23e The human body and its elements

(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

Rule 23e (continued)

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Rule 23e (continued)

(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 54 Novelty

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3)...

Article 56 Inventive step

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. …

Article 57 Industrial application

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

Article 83 Disclosure of the invention

The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Case studies for DNA claims

The following claim language is selected:

A polynucleotide sequence consisting of the nucleotide sequence of ...

Case A: Polynucleotide is derived from cDNA library. Can be used as probe. No other function is disclosed.

Case A

- Not patentable under EPC regulations (Rule 23e(3), also lack of inventive step, no industrial applicability)
- Not patentable under JP standards due to lack of inventive step, no industrial applicability
- Not patentable under US standards due to lack of inventive step, no utility

Case B

- Polynucleotide is derived from a cDNA library. Can be used as probe. Deduced amino acid sequence shows potential site of glycosylation, so that the corresponding gene may be structural. No other function is disclosed.

Case B

- Now patentable under EPC regulations
- Presumably not patentable under JP standards due to lack of inventive step, no industrial applicability
- Presumably not patentable under US standards due to lack of inventive step, no utility

Case C

Polynucleotide is a 500 bp long cDNA. The corresponding mRNA is expressed only in hepatocytes in patients having disease Y. Can be used as probe for disease Y.

Case C

- Patentable under EPC standards
- Patentable under JP standards
- Patentable under US standards

Case D

- A structural gene having a polynucleotide sequence consisting of the nucleotide sequence of ...
- The polynucleotide was obtained from cDNA library. The nucleotide sequence and deduced amino acid sequence showed 95 % homology to rat.
- Probe for full-length DNA encoding human protein. The rat DNA is known.

Case D

- Although not excluded from patentability under EPC, not patentable due to lack of inventive step
- Not patentable under JP standards due to lack of inventive step
- Not patentable under US standards due to lack of utility

What can be claimed?

- A DNA coding for a protein ...
- A DNA having a nucleotide sequence ... coding for a protein ...
- A gene comprising a nucleotide sequence ...
- An antisense oligonucleotide having the sequence ...
- A DNA regulating gene function...

What cannot be claimed according to EPC?

- A DNA having the nucleotide sequence ...
- A DNA fragment (without explained function) ...
- EST
- SNP