Patentability Requirements in Biotechnology

The EPO approach

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Biotechnology, EPO

Information Sources in Biotechnology
Key databases for patenting Biotechnology
24 July 2012, The British Embassy, Tokyo
The European Patent Convention

- 1973 – Diplomatic Conference in Munich
  - EPC signed by 16 countries

- 1977 – EPC enters into force in seven countries

- 2012 – **38 member states**

  Albania • Austria • Belgium • Bulgaria • Croatia • Cyprus • Czech Republic • Denmark • Estonia • Finland • France • Germany • Greece • Hungary • Iceland • Ireland • Italy • Latvia • Liechtenstein • Lithuania • Luxembourg • Former Yugoslav Republic of Macedonia • Malta • Monaco • Netherlands • Norway • Poland • Portugal • Romania • San Marino • Serbia • Slovakia • Slovenia • Spain • Sweden • Switzerland • Turkey • United Kingdom
The European Patent Convention (EPC) provides the legal framework for the granting of European patents via a centralised procedure with effect in 38 countries.
The European Patent Organization

The executive body
The Office is responsible for search-examination-opposition of European patent applications

The legislative body
Consists of delegates from the Member States and is responsible
• to adopt the budget
• to approve the President’s actions in implementing the budget
• to amend the Implementing Regulations and Rules
European Patent Office - EPO

Our mission
As the patent office for Europe, we support innovation, competitiveness and economic growth across Europe through a commitment to high quality and efficient services delivered under the European Patent Convention.

One of the big five Patent Offices worldwide with JPO, KIPO, SIPO and USPTO

http://www.epo.org/about-us/publications
Technical fields in DG Operations

Audio-Video Media

Electricity & Semiconductor Technology
- Electronics
- Handling and Processing
- Human Necessities
- Industrial Chemistry
- Polymers

Biotechnology

Civil Engineering & Thermodynamics
- Computers
- Measuring and Optics
- Pure and Applied Organic Chemistry
- Telecommunications
- Vehicles and General Technology

Biotech
240 examiners

The Hague

Munich

Munich

Munich

Munich

Munich
Technical fields\(^1\) of patent applications (2011)\(^2\)

1. Medical technology: 10,534
2. Electrical machinery, apparatus, energy: 8,963
3. Computer technology: 8,197
4. Digital communication: 7,843
5. Organic fine chemistry: 6,887
7. Transport: 6,231
8. Biotechnology: 5,865
9. Pharmaceuticals: 5,759
10. Telecommunications: 4,800

\(^1\) Classified according to the IPC and technology concordance table compiled by the Fraunhofer ISI for WIPO
\(^2\) Based on European patent applications filed with the EPO
Technical fields of Biotechnology

- Nine Directorates (six in Munich, DE; three in The Hague, NL)
- 240 Examiners
- Technical Areas covered:
  - Nucleic acid based analysis
  - Protein based analysis
  - Immunology: vaccines and antibodies
  - Cell lines, cell therapy, gene therapy
  - Genetically modified organisms (plants and animals)
  - Microorganisms and viruses
  - Peptides and their genes, enzymes, short peptides
  - Interfering RNA
Patent rights

- A patent is a legal title granting its holder the exclusive right to make use of an invention for a limited area and time stopping others from, among other things, making, using or selling it without authorisation.

- A patent holder,
  - as an exchange for making his invention known to the public,
  - is granted with monopoly rights to prevent others from exploiting his invention without his authorisation:
    - a passive right
    - a territorial right
    - a right of limited time
What is a patent?

• A patent is a legal title granting its holder the exclusive right to prevent third parties from exploiting an invention (making, using, offering for sale, selling or importing infringing products) without authorisation in a defined country and for a limited period, e.g. 20 years.

• In return for this protection, the holder has to disclose the invention to the public.
The grant procedure at a glance

Applicant

European patent application

Filing and formalities examination

Search and search report together with a preliminary opinion on patentability

Substantive examination

Grant of a European patent

Validation in the designated states

Refusal of the application

Opposition proceedings

Appeal proceedings

Public

Publication of the application and search report

Observations by third parties possible (Article 115 EPC)

Publication of the patent specification
Basic requirements of patentability

• **Novelty** (Article 54 EPC)
  – the claimed subject-matter must be new

• **Inventive step** (Article 56 EPC)
  – the invention must be not obvious for a skilled person working in the relevant field of technology
  – the invention must solve a technical problem

• **Industrial application** (Article 57 EPC)
  – the claimed subject-matter must be made or used in any kind of industry

• **Sufficiency of disclosure** (Article 83 EPC)
  – the description of the invention must be clear and complete so that a skilled person working in the relevant field of technology shall be able to reproduce it
Biotechnological Inventions – EU legislation

Directive 98/44/EC (July 1998)

EU legislation for harmonization among EU Countries and provision of legal certainty

http://eur-lex.europa.eu/

The Directive (entered into force 01.09.99; OJ EPO p.101, 1999) and is used as a supplementary means of interpretation of Rules 26 to 29 EPC
Patentability of biotechnological inventions (Rule 27 EPC)

- Biotechnological inventions shall be patentable if they concern
  - biological material which is isolated from its natural environment or technically produced even if it previously occurred in nature
  - plants or animals if not confined to a particular plant or animal variety
  - microbiological processes and products
Exceptions to patentability Article 53(a) EPC

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; 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

“Ordre public” T 0356/93
- Protection of public security, of the physical integrity of individuals, of the environment

Morality T 0356/93
- Morality is related to the totality of accepted norms of right and wrong in a particular culture. For the purposes of the EPC, the culture in question is the one inherent in European society and civilization

- “ordre public” and morality may vary in different cultures and with time
Exceptions to patentability Article 53(b) EPC

European patents shall not be granted in respect of:

(b) plants 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

(c) methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

- Surgery is understood to include methods which intentionally intervene in or disrupt the structure of the body
- Therapy is meant to prevent, cure or relieve a disease, illness, pain, discomfort, incapacity to restore an organism from a pathological state to its original condition
- to prevent a pathology
Therapeutic / surgical / diagnostic methods: Why such exclusion?

A patent confers a monopoly to the Proprietor; however, in the pharmaceutical/medical field:

- Medical practice must not be hindered by protection rights (need to ensure medical care for the population). The doctors must be free of practising their profession.

- Even though it may be commercial in nature, the medical profession is not a branch of industry.
Exceptions to patentability (Rule 28 EPC)

Exceptions to patentability under Article 53(a) EPC

- cloning of human beings

- modifying the human germ line

- industrial or commercial use of human embryos

- the generation of genetically modified animals if their production causes suffering without substantial medical benefit
Transgenic animals - The "Onco-mouse" case

Claim: A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal

- Filed 24.06.85, examined and refused for not disclosing how the method would be performed for all non-human mammalian animals
- Appeal: Board of Appeal decision T19/90 introduces the "balancing test" of weighing up the suffering of a transgenic animal versus the usefulness of the invention
- Granted on 13.05.92

- Opposition filed Feb 93 by 17 opponents including Green Party of Germany and Austria, Protestant Church of Germany, the British Union for the abolition of vivisection
- Oral proceedings held from 21.11.95 till 24.11.95 and again from 06.11.01 to 07.11.01
- Patent maintained in amended form which relates to rodents rather than to all mammalian animals since not all mammals may be used as test animals (decision published on 16.01.03)
- Appeal filed by 17 appellants, oral hearing took place on 05.07.04.
- With decision T 315/03 of 6th July 2004 (published April 2005 with total of 148 pages), the Board of Appeals established that transgenic animals limited to mice do not contravene EPC.
Refused by the Examining Division (June 2004)

Reasoning of the refusal

• The provisions of Rule 23d(c) (now R. 28 (c) EPC) in conjunction with Article 53(a) EPC are not directed exclusively to the claimed subject-matter but rather concerned inventions, thus including the methods that made the claimed subject-matter available to the public.

• The invention relies exclusively on use of human embryos for the production of the cells AND the generated cell cultures do not serve any therapeutic or diagnostic purpose useful to the embryo itself, thus, Recital 42 does not apply.
Human embryonic stem cells
WARF Case  EP 96903521

• The Applicant filed an appeal against the refusal by the Examining Division

• In decision T1374/04 (November 2005) the Technical Board decided to refer questions of law to the Enlarged Board of Appeal

• The decision of the Enlarged Board of Appeal is published as G2/06 on 25.11.2008
Human embryonic stem cells
Decision G2/06

The request for a preliminary ruling on the issue by the European Court of Justice was rejected for lack of an institutional link between the EPO appeal boards and the EU.

Rule 28(c) EPC (01.09.1999) applies retroactively. This Rule does not change the Law, it serves in interpreting Article 53 (a) EPC.

Rule 28(c) EPC forbids the patenting of uses and products involving human embryos, including cells derived therefrom.

Human stem cell cultures which at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos are not patentable.

This decision is not concerned with the general question of patentability of inventions relating to human stem cells or stem cell cultures.
The human body and its elements
(Rule 29 EPC)

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.

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

The industrial application of a sequence or partial sequence of a gene must be disclosed in the application.
Patentability of gene sequences
Directive 98/44/EC

- Recital 22: Same criteria of patentability as in all other areas of technology (N, IS, IA); the industrial application must be disclosed in the application as filed.

- Recital 23: A mere nucleic acid sequence without indication of a function does not contain technical information and is therefore not a patentable invention.

- Recital 24: When the gene is used to produce a protein, in order to comply with the IA criterion, it is necessary to specify which protein is produced and what function it performs.
The Board considered that:

- new protein BDP1 was said to play a possible role in cellular housekeeping and in certain types of cancer

- however, the application does not suggest an anti-cancer activity nor a therapeutic use as tumour suppressor agent

- post published evidence, even 7 years after filing of the application still does not confirm any specific role for BDP1 indicating on-going research

and decided that:

- when a substance is naturally occurring in the human body and it is structurally characterized and made available but either its function is not known or it is so complex and incompletely understood and no disease or condition has been yet identified as being attributable to an excess or deficiency of the substance and no other practical use is suggested, then industrial application cannot be acknowledged

- a profitable use of an isolated substance should be disclosed

- vague and speculative indication of possible objectives that might or might not be achievable by carrying out further research with the tool as described is not sufficient for the fulfilment of Art. 57 EPC
Claims to gene sequences – practical examples

1) An isolated nucleic acid molecule coding for calcium channel C1 characterized by SEQ ID NO:1 ✓

2) An isolated nucleic acid molecule coding for calcium channel C1 and has 70% identity to SEQ ID NO:1 ✓

3) An isolated polypeptide having calcium channel C1 function and characterized by SEQ ID NO:2 ✓

1) Nucleic acid molecule hybridizing with SEQ ID NO:1 ×

2) Nucleic acid molecule 70% homologous to SEQ ID NO:1 ×

3) Nucleic acid fragments of SEQ ID NO:1 ×

4) Functional analogues or variants of the polypeptide with SEQ ID NO:2 ×
Thank you!

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