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Swiss Federal Institute of Intellectual Property

Typical Patent Claims of Biotechnological Inventions

Red biotechnology (Medicine)

- bioengineered drugs
- gene therapy
- molecular diagnostics
- stem cell therapy

… 55%

White biotechnology (Industrial)

- biofuels
- biodegradable plastics
- environmental remediation

… 41%

Green biotechnology (Agriculture)

- transgenic plants
- ecological tools

… 4%

Blue biotechnology (Marine)

- aquaculture
- Cosmetics from algae

… ?

% patents in biotechnology *

* (https://www.epo.org/news-issues/issues/biotechnology-patents.html)

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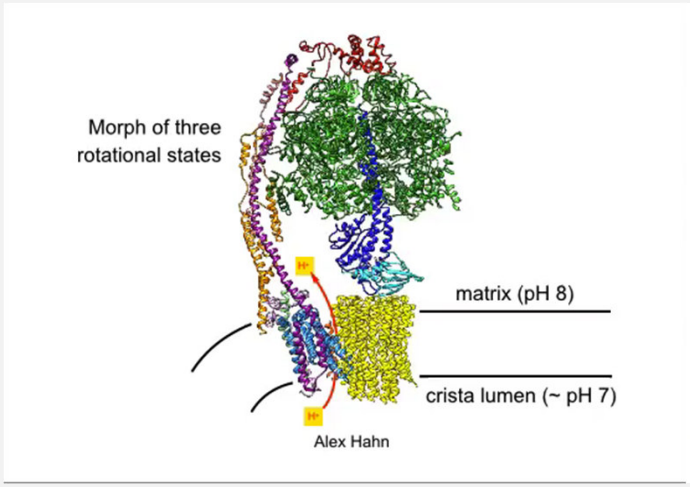
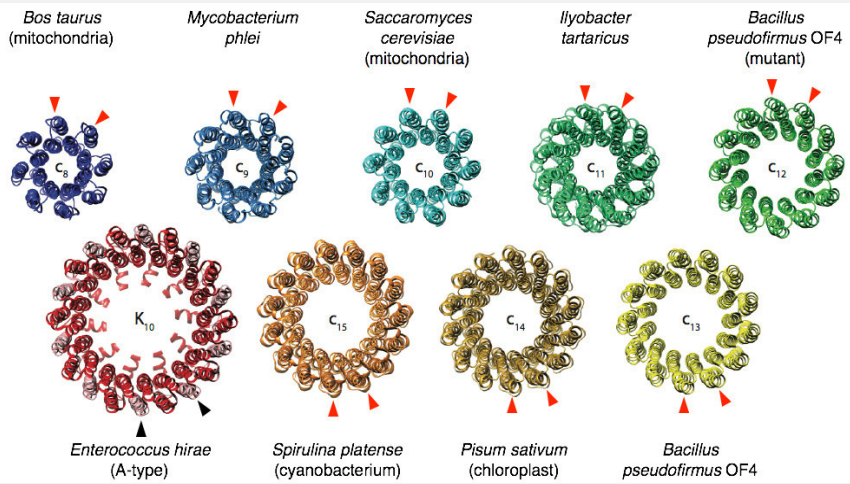
Typical Patent Claims of Biotechnological Inventions

Bios *=> life;* ***tecne*** *=> skill;* ***logia*** *=> science*





Figures taken from: https://www.biophys.mpg.de/en/sb/atp-synthases.html

UN Convention on Biological Diversity, Art. 2

- "*any technological application that* ***uses biological systems, living organisms****, or* ***derivatives thereof,*** *to make or modify* ***products or processes for specific use***"

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Typical Patent Claims of Biotechnological Inventions

Europäisches Patentamt
European Patent Office
Office européen des brevets

What are biotechnological inventions?

Inventions that relate to the **industrial use** of **biologically active material** derived from **living organisms**, and the **use of such organisms**.

According to ***Rule 26 (3) EPC***, biotechnological material is any material **containing genetic information** and being capable of **reproducing** itself or **being reproduced** in a **biological system**.

Legal basis for biotechnological inventions?

Rules 26-29 EPC

EPC Chapter V

- *Rule 26 EPC defines the term "biotechnological inventions" and its scope.*
- *Rule 27 EPC provides a non-exhaustive list of patentable inventions.*
- *Rule 28 EPC gives non-exhaustive examples for non-patentable inventions.*
- *Rule 29 EPC is specifically addressed to inventions concerning the human body and its elements.*

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Typical Patent Claims of Biotechnological Inventions

Swiss Patent Law Art 2

§ 1 **Patentability exclusions** of invention:

- **against public order**
- **violation of human dignity** e.g.
  - **a. Cloning of humans**
  - **b. Production of human chimera** by the use of **human germ**, **totipotent or embryonal stem cells**
  - c. Parthenogenesis using **human germ cells**
  - d. Changing **genetic identity** of a **human being and the changed germ cells**
  - e. Unchanged human **embryonal stem cells**
  - **f. Use of human embryos** for non-medical purpose
  - g. Change of genetic identity of animals that leads to **unbearable suffering**

  However, transgenic animals carrying human genes or organs are patentable

§ 2 **Patentability exclusions** of:

- **Therapeutic** or **surgical treatments** on **the human or animal body**
- **diagnostic** processes **on the human or animal body**
- or **the use of either**

Typical Patent Claims of Biotechnological Inventions

Swiss Patent Law Art 49a

II. information on the **source of genetic resources** and **traditional knowledge**

[1] The **patent application must contain information** about the source:

a. the **genetic resource** to which the inventor or patent applicant has had access, **if** the **invention** is **based directly** on that resource;

b. **traditional knowledge** of indigenous or local communities **about genetic resources** to which the inventor or patent applicant had access**, if the invention is directly based** on such knowledge.

[2] If the **source is not known** to either the inventor or the patent applicant, the patent **applicant shall confirm this in writing**.

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Typical Patent Claims of Biotechnological Inventions

Like other patents biotechnology patents contain:

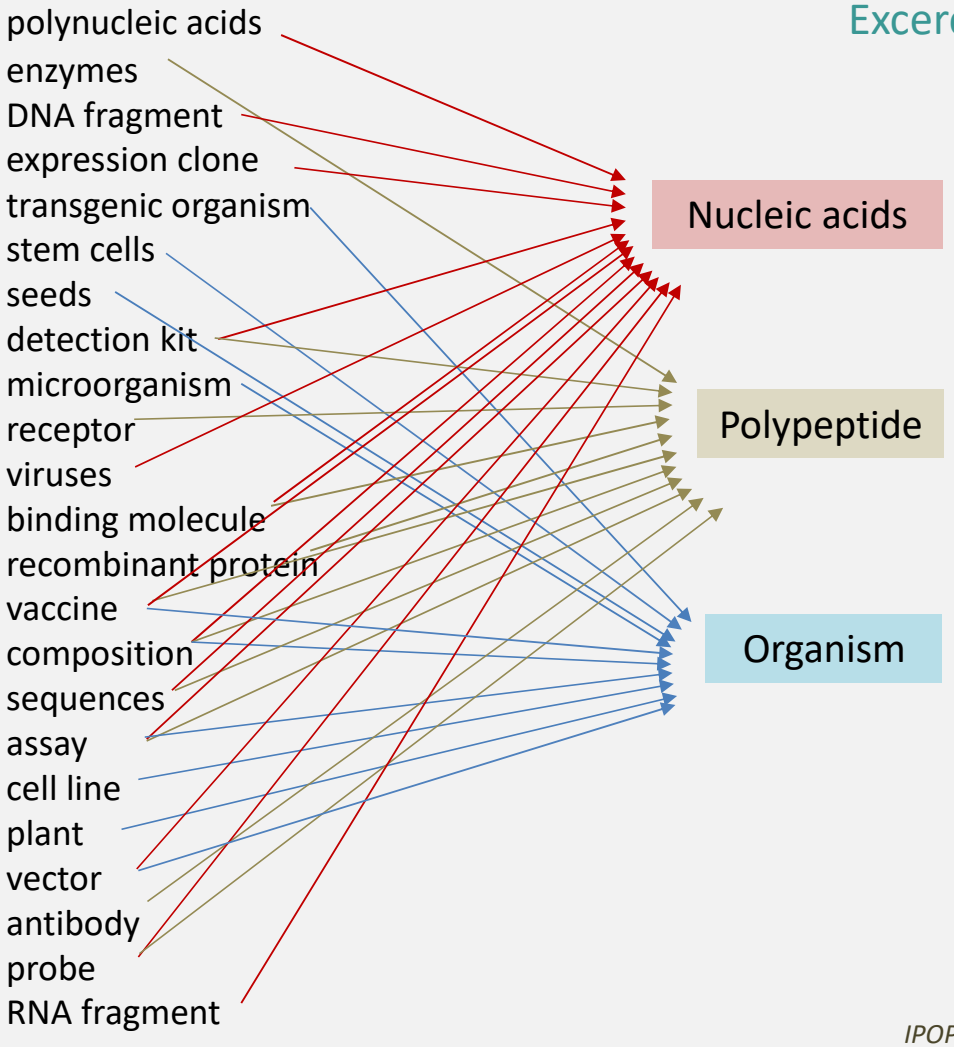
- A **description** of the invention itself with specific details and the **advantages** that this invention brings in **comparison** with the **known state of the art** and **examples**;

- A **set of claims** which define the matter for which **protection** is sought. In biotechnology claims are mostly concerned with:
  - o **Product** claims
  - o **Use** claims
  - o **Method** of production claims

However, the inventions mainly comprise **at least** one of the following **product features** …

Nucleic acids and polypeptides have to be defined by their sequence (e.g. SEQ ID NO: 1)

Excercise



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Typical Patent Claims of Biotechnological Inventions

Excercise

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  - o **Product** claims
  - o **Use** claims
  - o **Method** of production claims

EP1448595 (B1) — 2006-10-18

Claim
1. A polypeptide having antimicrobial activity selected from the group consisting of:

(a) a polypeptide comprising an amino acid sequence which has at least *65% identity* with amino acids 1 to 40 of **SEQ ID NO:2**;

(b) a polypeptide which is encoded by a nucleotide sequence which hybridizes under medium *stringency conditions using 0.2 x SSC at 42°C* for washing with a polynucleotide probe selected from the group consisting of:
(i) the complementary strand of nucleotides 166 to 285 of **SEQ ID NO:1**,
(ii) the complementary strand of nucleotides 70 to 285 of **SEQ ID NO:1** and
(iii) the complementary strand of nucleotides 1 to 285 of **SEQ ID NO:1**; and

(c) a fragment of (a) or (b) that has antimicrobial activity.

What are the main features in EP1448595 (B1) ?

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Typical Patent Claims of Biotechnological Inventions

Main features of EP1448595 (B1) — 2006-10-18 :

(a) Polypeptide
(at least 65% identity) with amino acids 1 to 40 of **SEQ ID NO:2**

Amino acid (aa)

antimicrobial activity

(b) encoded by a nucleotide sequence (*which hybridizes under medium stringency conditions using 0.2 x SSC at 42°C for washing with a polynucleotide probe selected from the group consisting of):*

(i) the *complementary strand* of nucleotides 166 to 285 of **SEQ ID NO:1**
(ii), (iii) …

Defined as **nucleotides (nt)** or as **base pairs (bp)**

Reminder:
DNA encodes in **triplets** of **nucleotides** containing **bases**:

- adenine (A, a)
- thymine (T, t) (RNA t -> u, uracil)
- guanine (G, g)
- cytosine (C, c)

… for **one amino acid *(20 proteinogenic amino acids*)***

Start codon: atg -> Met (methionine, M)

```
atg caa ttt acc acc atc ctc tcc atc ggt
Met Gln Phe Thr Thr Ile Leu Ser Ile Gly
```

M Q F T T I L S I G …

(single letter code)

Stop codon: tag, taa, tga

**(22 including selenocysteine and pyrrolysine)*

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Typical Patent Claims of Biotechnological Inventions

Excercise

Main features of EP1448595 (B1) — 2006-10-18 :

(a) Polypeptide
(at least 65% identity) with amino acids 1 to 40 of **SEQ ID NO:2**

Amino acid (aa)

antimicrobial activity

(b) encoded by a nucleotide sequence (*which hybridizes under medium stringency conditions using 0.2 x SSC at 42°C for washing with a polynucleotide probe selected from the group consisting of):*

(i) the *complementary strand* of nucleotides 166 to 285 of **SEQ ID NO:1**
(ii), (iii) …

Defined as **nucleotides (nt)** or as **base pairs (bp)**

Claimed sequences have to be disclosed !

SEQ ID NO: 2
1 – 124 aa
MQFTTILSIG ITVFGLLNTG AFAAPQPVPE AYAVSDPEAH PDDFAGMDAN
QLQKRGFGCN GPWDEDDMQC HNHCKSIKGY KGGYCAKGGF VCKCY

SEQ ID NO: 1
1 – 288 bp
ATGCAATTTA CCACCATCCT CTCCATCGGT ATCACCGTCT TCGGACTTCT
CAACACCGGA GCCTTTGCAG CACCCCAGCC TGTTCCCGAG GCTTACGCTG
TTTCTGATCC CGAGGCTCAT CCTGACGATT TTGCTGGTAT GGATGCGAAC
CAACTTCAGA AACGTGGATT TGGATGCAAT GGTCCTTGGG ATGAGGATGA
TATGCAGTGC CACAATCACT GCAAGTCTAT TAAGGGTTAC AAGGGAGGTT
ATTGTGCTAA GGGGGGCTTT GTTTGCAAGT GTTACTAG

Typical Patent Claims of Biotechnological Inventions

EP2001277 (A2) — 2008-12-17

1. An isolated nucleic acid molecule comprising a nucleic acid sequence encoding an acyl-CoA synthetase (ACoAS) that catalyzes the conversion of long chain PUFA free fatty acids (FFA) to acyl-CoA, wherein the nucleic acid sequence encodes an acyl-CoA synthetase (ACoAS) that is at least 75% identical to an ACoAS having an amino acid sequence of **SEQ ID NO:83**.

6. An isolated protein encoded by the nucleic acid molecule of anyone of Claims 1 to 5.

7. A recombinant nucleic acid molecule, comprising the nucleic acid molecule according to anyone of Claims 1 to 5, operatively linked to an expression control sequence.

8. A recombinant host cell comprising the recombinant nucleic acid molecule of Claim 7.

9. The recombinant host cell of Claim 8, wherein the host cell is a microorganism or plant cell.

10. A genetically modified microorganism or a genetically modified plant, wherein the microorganism or the plant has been genetically modified to express the isolated nucleic acid molecule of anyone of Claims 1 to 5.

Excercise: what are the main features?

- Isolated nucleic acid
- ACoAS, conversion of fatty acids to acyl-CoA
- 75% identity to SEQ ID NO: 83
- Isolated protein
- Recombinant nucleic acid molecule
- Recombinant host cell
- Microorganism or plant cell
- Genetically modified cell

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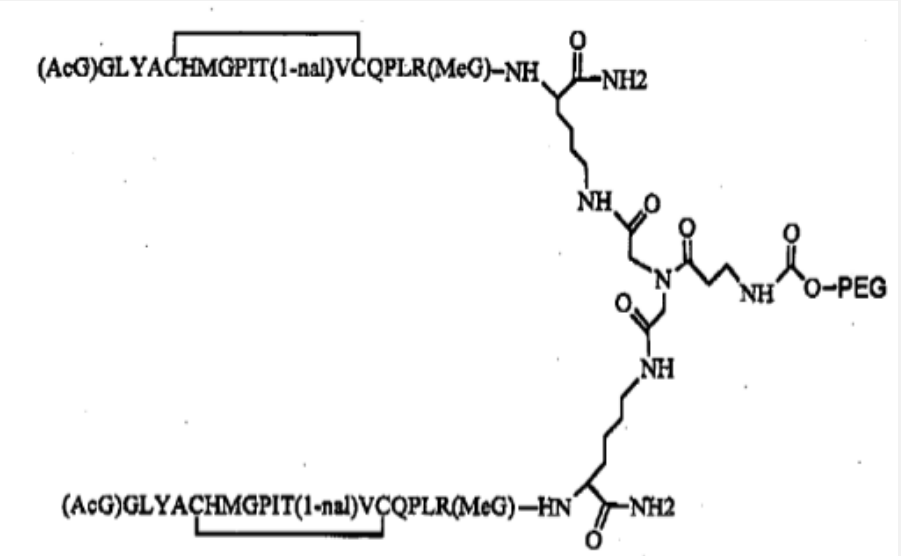
Typical Patent Claims of Biotechnological Inventions

Excercise: what are the main features?

EP1629007 (B1) — 2009-04-15

Claims

1. A compound that binds to and activates the erythropoietin receptor (EPO-R), which compound comprises a peptide dimer having the formula:



wherein

(i) in each peptide monomer of the peptide dimer, each amino acid is indicated by standard one letter abbreviation, AcG is N-acetylglycine, and 1-nal is 1-naphthylalanine;

(ii) each peptide monomer of the peptide dimer contains an intramolecular disulfide bond between the two cysteine (C) residues of each monomer

(iii) ["PEG"] comprises at least one linear polyethylene glycol (PEG) moiety, each PEG moiety having a molecular weight of about 20,000 to about 40,000 Daltons.

Typical Patent Claims of Biotechnological Inventions

Excercise: what are the main features?

EP1629007 (B1) — 2009-04-15

Claims

1. A compound that binds to and activates the erythropoietin receptor (EPO-R), which compound comprises a peptide dimer having the formula:

wherein

(i) in each peptide monomer of the peptide dimer, each amino acid is indicated by standard one letter abbreviation, AcG is N-acetylglycine, and 1-nal is 1-naphthylalanine;

(ii) each peptide monomer of the peptide dimer contains an intramolecular disulfide bond between the two cysteine (C) residues of each monomer

(iii) ["PEG"] comprises at least one linear polyethylene glycol (PEG) moiety, each PEG moiety having a molecular weight of about 20,000 to about 40,000 Daltons.

- Compound
- Activates EPO-R
  "treat disorders associated with insufficient or defective red blood cell production"
- Peptide dimer
  (**G**GLYACHMGPIT**A**VCQPLRG)x2
- disulfide bond
- PEG

Typical Patent Claims of Biotechnological Inventions

Excercise: is this a biotech invention?

EP1629007 (B1) — 2009-04-15

Claims
1. A compound that binds to and activates the erythropoietin receptor (EPO-R), which compound comprises a peptide dimer having the formula:

wherein
(i) in each peptide monomer of the peptide dimer, each amino acid is indicated by standard one letter abbreviation, AcG is N-acetylglycine, and 1-nal is 1-naphthylalanine;
(ii) each peptide monomer of the peptide dimer contains an intramolecular disulfide bond between the two cysteine (C) residues of each monomer
(iii) ["PEG"] comprises at least one linear polyethylene glycol (PEG) moiety, each PEG moiety having a molecular weight of about 20,000 to about 40,000 Daltons.

Check the description!

[0062] The peptides of the invention may be prepared by classical methods known in the art. These standard methods include exclusive solid phase synthesis, partial solid phase synthesis methods, fragment condensation, classical solution synthesis, **and recombinant DNA technology** [See,e.g., Merrifield J. Am. Chem. Soc. 1963 85:2149].

→ Possibly yes

Typical Patent Claims of Biotechnological Inventions

EP1870459 (A1) — 2007-12-26

Excercise: what are the main features?

Claims

1. A method for producing a polypeptide comprising a mutation in an amino acid residue forming a polypeptide interface such that polypeptide association will be regulated, wherein the method comprises:
(a) modifying a nucleic acid encoding an amino acid residue forming the polypeptide interface from the original nucleic acid, such that polypeptide association will be inhibited;
(b) culturing host cells such that said nucleic acid is expressed; and
(c) recovering said polypeptide from the host cell culture.
…
75. An antibody comprising a heavy chain variable region and a light chain variable region, wherein the following amino acid residues of (1) and (2) carry the same type of charge:
(1) an amino acid residue which is included in the heavy chain variable region and corresponds to position 39 in the amino acid sequence of **SEQ ID NO: 6**; and
(2) an amino acid residue which is included in the light chain variable region and corresponds to position 44 in the amino acid sequence of **SEQ ID NO: 8**.
…
94. A composition comprising the antibody of claim 87 and a pharmaceutically acceptable carrier.
95. A nucleic acid encoding a polypeptide constituting the antibody of claim 87.
96. A host cell comprising the nucleic acid of claim 95.
97. A method for producing the antibody of claim 87, which comprises the steps of culturing the host cell of claim 96, and recovering the polypeptides from the cell culture.

Typical Patent Claims of Biotechnological Inventions

EP1870459 (A1) — 2007-12-26

Claims
1. A method for producing a polypeptide
mutation in an amino acid
polypeptide association will be inhibited;
host cells
said nucleic acid is expressed
recovering said polypeptide
…
75. An antibody
heavy chain variable region position 39 of **SEQ ID NO: 6**
light chain variable region position 44 of **SEQ ID NO: 8**
…
94. A composition, antibody and carrier.
95. A nucleic acid encoding the antibody
96. A host cell
97. A method for producing the antibody
culturing the host cell
recovering the polypeptides

Example of a

reach-through claim

typical for biotechnological inventions

Typical Patent Claims of Biotechnological Inventions

EP1870459 (A1) — 2007-12-26

Claims
1. A method for producing a polypeptide
mutation in an amino acid
polypeptide association will be inhibited;
host cells
said nucleic acid is expressed
recovering said polypeptide
…
75. An antibody
heavy chain variable region position 39 of **SEQ ID NO: 6**
light chain variable region position 44 of **SEQ ID NO: 8**
…
94. A composition, antibody and carrier.
95. A nucleic acid encoding the antibody
96. A host cell
97. A method for producing the antibody
culturing the host cell
recovering the polypeptides

What are the basic requirement for a patent ?

- Novelty → perform a search
- Inventiveness → combine documents
- Disclosure → check description
- Clarity → what shall be protected?
- Unity → is it the same invention?

… Discussion …

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