

The European Patent Office

Patent protection of inventions relating to protein expression systems

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Directorate (2.4.03)

28-30.09.2009



Protein Expression Systems



Protein expression systems typically **comprise:**

- nucleic acid of interest (NOI)
- expression vector
- transformation / transfection means
(e.g. liposomes, etc.)
- host cells,
- growth media
- isolation means (e.g. affinity means:
antibody)
- product, i.e. protein

The European Patent Convention (EPC)

Claims must:

- clearly define the invention in terms of technical features (Art. 84 EPC)
- contents of claims must differ by at least one technical feature from the prior art: novelty (Art. 54 EPC)
- involve inventive step (Art. 56 EPC)
- be supported in an enabling manner over the entire width (Art. 83 EPC).

Novelty of expression systems

- new NOI: e.g. new gene, mutant or tagged variant
(SEQ ID NO. or deposit number)
- new vector: e.g. new promoter, enhancer, new viral vector
(SEQ ID NO. or deposit number)
- new transfection/transformation means: liposomes, virus-like particles
(chemical formulae, SEQ ID NO.)
- new bacterial strain, new host cell line
(deposit number)

Novelty of expression systems

- new growth media, new additive
(chemical formulae, concentrations)
- new antibody or new affinity means
(deposit number)
- new protein
(SEQ ID NO.)

None of the above: most likely it is a **Selection Invention**

Not everything new is inventive!

- non-obvious alternative:

e.g. viral expression vector with a moss-derived promoter

- obvious alternative:

e.g. viral expression vector with a promoter of another virus

nevertheless **inventive** if:

1) unexpected effect (e.g. higher yield or purity of product)

2) overcoming of unexpected difficulties

(e.g. well known vector X combined with well known,
heterologous promoter Y, but

the inventor found out that it necessarily requires an enhancer Z)

What could be claimed?

Claim to the expression system comprising:

- the known vector X,
- the heterologous promoter Y

could be new but not inventive!

Acceptable claim could be directed to the expression system comprising:

- the known vector X,
- the heterologous promoter Y, and
- **an enhancer Z,**

even, if the combination of the vector and promoter renders novelty of claim

... and not every invention is new!

3) overcoming of a prejudice in the art (e.g. promoter X requires enhancer to give a reasonable yield).

Inventor found out that promoter X gives a reasonable yield without any enhancer.

Yet, claim to expression system **comprising** promoter x lacks novelty although it covers an invention.

How to overcome this problem?

... and not every invention is new!

E.g. Disclaimer:

expression system comprising prompter X and no enhancer.

Use of operating conditions in Selection invention

All structural elements of in the combination of the expression system are not new, yet there could be a patentable invention.

Example:

- parameter A: optimised salt concentration which is in a sub-range of the concentration range disclosed in the prior art
- parameter B: optimised temperature/time of incubation which is a sub-range of the range disclosed in the prior art

What could be an acceptable claim?

Use of operating conditions in Selection invention

Claim to a **method** of expression comprising the steps of:

- incubation in the optimised range of salt concentration,
- incubation at the optimised temperature
- incubation for the optimised time of incubation.

In case of operating conditions, there must be a special effect, i.e. selection is purposeful!

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Thank you for your attention !

