

Written description of inventions and practical tips for US applications

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Content

- 1. Patent System**
- 2. Content of Patent**
- 3. 35 USC §112**
- 4. Practical tips for drafting patent applications**
- 5. Confidentiality vs Disclosure**

1. Patent System – U.S. vs China

| U.S. | | China | |
|---------|----------------|--------------------|----------|
| Utility | 20 years | Invention 发明专利 | 20 years |
| Design* | 14 or 15 years | Design 外观设计专利 | 10 years |
| Plant | 20 years | / | |
| / | | Utility model 实用新型 | 10 years |

* U.S. design app'l filed on or after May 13, 2015 have a term of 15 years from issuance

Utility patent - Any new and useful **process, machine, manufacture, or composition of matter**, or any new and useful improvements thereof

A right granted by the government to an inventor to **exclude** others, for a fixed period of time, from making, using, selling, importing, or offering for sale the patented products, or using the patented method, or using, offering for sale, selling or importing the products made by the patented method.

2. Content of Patent

- Title of the invention
- Abstract
- Background of the invention
- Summary of the invention
- Description of figures
- Detailed description of the invention
- Sequence listing
- Experimental details
- Claims
- *Figures*

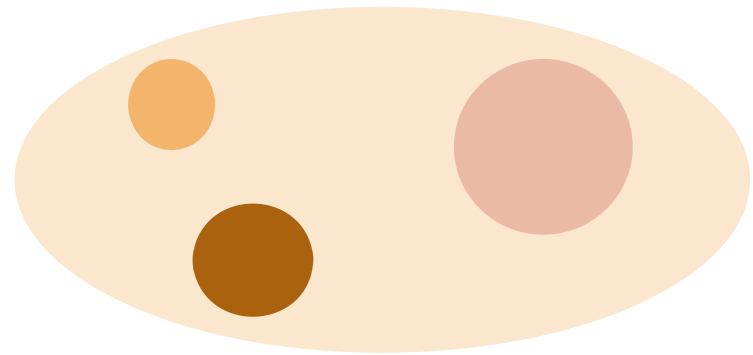
3. 35 U.S.C. 112 (a) Specification

- Separated requirements:
 - Written description
 - Enablement
 - Best mode

- The specification shall contain a **written description** of the invention, and of the manner and process of making and using it, in such **full, clear, concise, and exact** terms as to **enable** any person skilled in the art to which it pertains, or with which it is most nearly connected, **to make and use the same**, and shall set forth the **best mode** contemplated by the inventor or joint inventor of carrying out the invention.

Written Description

- Inventor's obligation to disclose
- Possession of the claimed invention
- Species to Genus
- Species to Species
- Whether the description of limited species adequately describe the genus?



Green fluorescent protein

US Patent 5,491,084

Filed on Sep 10, 1993

Granted on Feb 13, 1996

- The Nobel Prize in Chemistry 2008
- Osamu Shimomura, Martin Chalfie, Columbi & Roger Y. Tsien

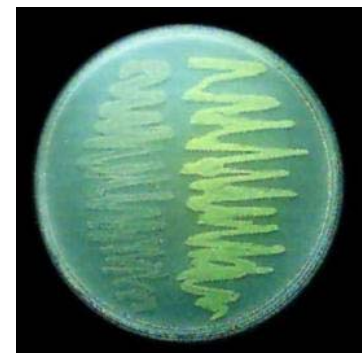
Expressed in *E. Coli* and *C. elegans*



What is claimed is:

1. A host cell comprising a DNA molecule having a regulatory element from a gene, other than a gene encoding an *Aequorea victoria* green-fluorescent protein operatively linked to a DNA sequence encoding the fluorescent *Aequorea victoria* green-fluorescent protein.

2. A cell of claim 1, wherein the cell is selected from a group consisting of bacterial cell, yeast cell, fungal cell, plant cell or animal cell.



Written Description

- Suggestions:
 - Representative no. of species must be given
 - Common features to describe the entire genus
 - Reflect variations within genus

Enablement Requirement

- How to make and how to use the invention?
- Extrapolation of examples
 - *In vitro vs in vivo*
 - One species to another
 - Species vs genus
 - Whether the results are predictable in the art?
 - Sufficient for one to make & use the invention?
 - Convincing to attain said effect?

Best mode

- Adequate description of the means for carrying out the invention
- Best mode means that the specification **must disclose** the best mode of making and practicing the invention as the inventors contemplate, although it is **not necessary to point out** the best mode embodiment (see MPEP §2165.01).

U.S. VS China

| | |
|-----------------------|---------------------------|
| 35 USC 112 (a) | 中国专利法第26条第3款 |
| Written Description | 说明书应当对发明或者实用新型作出清楚、完整的说明， |
| Enablement | 以所属技术领域的技术人员能够实现为准。 |
| Best mode | -- |

4. Practical tips for drafting patent applications

- Claims
- Comparison with prior art

Claims

- Define the scope of your rights
- Independent claim
 - Broadest, stand alone
- Dependent claim
 - Incorporating additional features into the independent claim
- Precise

Claims

Important features of invention

Connection of features

Type of claims

- Product claims - Catalyst X, recombinant interferon, device...
- Method/process claims
 - A method for oxidation, comprising the steps of (a), (b), (c)
 - A method for treating a disease in a subject comprising....
 - A process for production of catalyst X, comprising the steps of
 - A process for production of a recombinant interferon comprising:
- Product-by-process claims
 - A recombinant interferon produced by a method comprising:

Importance of limitations

- Temperature, concentration, list of similar or equivalent features etc

US Patent 5,491,084

What is claimed is:

1. A host cell comprising a DNA molecule having a regulatory element from a gene, other than a gene encoding an *Aequorea victoria* green-fluorescent protein operatively linked to a DNA sequence encoding the fluorescent *Aequo-rea victoria* green-fluorescent protein. 15

2. A cell of claim 1, wherein the cell is selected from a group consisting of bacterial cell, yeast cell, fungal cell, plant cell or animal cell. 20

3. A cell of claim 1, wherein the regulatory element is a promoter.

4. A cell of claim 3, wherein the promoter is activated by a heavy metal. 25

5. A cell of claim 3, wherein the promoter is a P450 promoter.

6. A cell of claim 3, wherein the promoter is from a gene encoding a stress protein.

7. A cell of claim 6, wherein the stress protein is a heat-shock protein. 30

8. A cell of claim 1, wherein the regulatory element is an enhancer.

9. A method for selecting cells expressing a protein of interest which comprises: 35

- (a) introducing into the cells a DNAI molecule having DNA sequence encoding the protein of interest and DNAII molecule having DNA sequence encoding an

10. A method for selecting cells expressing a protein of interest which comprises:

- (a) introducing into the cells a DNAI molecule having DNA sequence encoding the protein of interest and DNAII molecule having DNA sequence encoding an *Aequorea victoria* green-fluorescent protein;

- (b) culturing the introduced cells in conditions permitting expression of the *Aequorea victoria* green-fluorescent protein and the protein of interest; and

- (c) selecting the cultured cells which express *Aequorea victoria* green-fluorescent protein, thereby selecting cells expressing the protein of interest,

wherein the cells are selected from a group consisting of yeast cells, fungal cells, insect cells, nematode cells, plant or animal cells.

11. A method for localizing a protein of interest in a cell which comprises:

- (a) introducing into a cell a DNA molecule having DNA sequence encoding the protein of interest linked to DNA sequence encoding an *Aequorea victoria* green-fluorescent protein such that the protein produced by the DNA molecule will have the protein of interest fused to the *Aequorea victoria* green-fluorescent protein;

- (b) culturing the cell in condition permitting expression of

Claims - Scope of Protection

- Genus claims vs Species claims
- Open vs Closed
- New claims & Amended claims

- Worked out by patent attorney in collaboration with inventor

Comparison with prior art

- New features
- Different from prior art
- Advantages over prior art
- Unexpected results/properties
- Teach away

5. Confidentiality vs Disclosure

- First-to-file system in US
- Publication vs Filing date
- 1-Year grace period
- File US Provisional Application

Summary

- Witten disclosure
- Scope of protection
- Prior art comparison

THANK YOU!

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