

## Significant Amendments to the Patent Examination Guidelines With Respect To Biotech Inventions

*By Meng Fanhong*

In 2006, the Chinese Patent Office (“CPO”) will again revise the Patent Examination Guidelines (“Guidelines”). According to the draft for public opinions published by the CPO, there will be big amendments to provisions relating to the examination of biotech inventions. For example, the Guidelines for the first time includes provisions giving guidance to the drafting of claims for genes and proteins, a long awaited feature. In addition, the revision also deals with the patentability of human embryonic stem cells such as those studied by the disgraced Dr. Woo-Suk Hwang of Korea. The amendments also clarify the meaning of the animal and plant varieties.

The Guidelines provide that the claims of the inventions relating to genes, carriers, recombinant carriers, transformants, peptides or proteins, fused proteins and monoclonal antibodies should be drafted as follows:

### **I. Gene**

1. Directly define the gene by its base sequences.
2. Define the gene with the amino acids of the peptides or proteins which it codes if the gene is a construct one.
3. The gene can be described by directly referring to the sequence listing or the figures if the base sequence of the gene or the amino acids of the peptide or the protein it codes are illustrated in the sequence listing or the figures.

For example: A DNA molecule, whose base sequence is illustrated in SEQ ID NO: 1 (or figure 1).

4. Define the gene by means of “substitution, deletion or addition” together with a

functional phrase. In particular:

A gene coding the following protein (a) or (b):

- (a) a protein comprising the amino acids Met-Tyr-...Cys-Leu;
- (b) a protein derived from protein (a) by substituting, deleting or adding one or more amino acids where the derived protein (b) retains the activity of enzyme A, and in which, protein (a) has the activity of enzyme A.

The criteria for allowing the above claims are as follows:

- 1) Derived protein (b) is defined by “substitution, deletion or addition of one or more” in the specification, especially the examples.
  - 2) The method of preparing protein (b) and the method of detecting its function is recorded in the description. Otherwise, the description will be deemed to have not been sufficiently disclosed.
5. Defining the manner of “hybridizing under stringent conditions” together with functional wording. In particular:

Gene (a) or (b), defined as follows:

- (a) a DNA molecule which is illustrated as the nucleotide sequence of ATGTATCGG....TGCCT;
- (b) a DNA molecule which hybridizes with that of (a) under stringent conditions and which codes a protein with the activity of enzyme A.

The criteria for allowing the above claims are as follows:

- (a) There is a detailed description of “stringent conditions” in the description.
  - (b) There is a definition of the DNA molecule of (b) in the description, especially in the examples.
6. A gene can also be defined by its function, physical or chemical features, the origin of the gene and the method for preparing the gene.

The following types of claims are not allowed:

- 1) A gene or DNA molecule, which has X% homogeneity with a sequence such as that listed in figure 1.
- 2) A gene or DNA molecule, which has X% homogeneity with a sequence such as that listed in figure 1, and it has certain functions.

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**II. Carrier**

1. Defining the carrier by its base sequence.
2. Defining the carrier by means such as a cleavage map, molecular weight, number of base pairs, origin of the carrier, a method for producing the carrier and the function and features of the carrier.

**III. Recombinant carrier**

It can be defined by the combination of at least a gene and a carrier.

**IV. Transformant**

It can be defined by the host and the gene or recombinant carrier that is introduced into the host.

**V. Peptide or protein**

1. Define the peptide or protein by its amino acid sequence or by the base sequence of the gene that codes the amino acid sequence.
2. The peptide or protein can be described by directly referring to the sequence listing or the figures if the amino acid sequence of the peptide or the protein has been depicted in the sequence listing or in the figures.

For example: A protein, whose amino acid sequence is illustrated in SEQ ID NO: 2 (or figure 2).

3. Define the gene by way of “substitution, deletion or addition” together with a functional phrase. For instance:

A protein of the categories (a) or (b) as follows:

- (a) a protein which comprises the amino acids Met-Tyr-...Cys-Leu;
- (b) a protein derived from protein (a) by substituting, deleting or adding one or more amino acids while the derived protein (b) retains the activity of enzyme A, and in which, protein (a) has the activity of enzyme A.

The criteria for allowing the above claims are as follows:

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- 1) Derived protein (b) is defined by “substituting, deleting or adding one or more” in the specification, especially in the examples.
  - 2) The method of preparing protein (b) and the method of demonstrating its function is recorded in the description. Otherwise, the description will be deemed to have not been sufficiently disclosed.
4. A protein can also be defined by its function, physical or chemical features, the origin of the protein and the method for preparing the protein.

## **VI. Fused cells**

A fused cell can be defined by the parent cell, the function or feature of the fused cells, or by the method of preparing the fused cells.

## **VII. Monoclonal antibody**

A monoclonal antibody can be defined by hybridoma from which the antibody is derived.

For example: A monoclonal antibody against antigen A, which is produced by a hybridoma and the deposition number of the hybridoma is CGMCC XXX.

The above drafting provisions are substantially consistent with the current practice in China. However, patent applicants should take note of the following issues:

- (1) There should be included in the detailed description the definition of “one or more” and the process for detecting the derived proteins in the description, if the applicant wants to draft a claim by means of “substitution, deletion or addition” together with a functional definition.
- (2) Based on the author’s experience, a claim defined by the homogeneity together with a functional phrase was previously allowable in China, especially when the degree of homogeneity is very high, such as 95% or more. However, according to the revised Guidelines, such a claim is no longer acceptable. This may have something to do with the uncertainty of claims defined by homogeneity.

In addition to the forgoing, the amendments also touch on the patentability of certain subject matter in the biotech field. One is the human embryonic stem cell and the other is animal and plant varieties.

- (1) For reasons of social ethics, human embryonic stem cells and the methods for preparing the same are not patentable in China according to Article 5 of the Patent Law.

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- (2) Human bodies in various phases of development including the germ cells, zygotes, and embryos are not patentable according to Article 5 of the Patent Law.
- (3) An animal in various phases of development including the germ cells, zygotes and embryos are covered by the concept of animal variety and is not patentable according to paragraph 1, subsection (4) of Article 25 of the Patent Law. However, somatic cells, tissues and organs of the animal are all allowable.
- (4) A plant and its reproductive materials such as seeds, which can maintain its life through synthesizing carbohydrates and proteins from water, carbon dioxide and inorganic salts by photosynthesis are covered by the concept of plant variety. According to paragraph 1, subsection (4) of Article 25 of the Patent Law, they are not patentable. However, the cells, tissues or organs of a plant can be patented.
5. The concepts of animal variety and plant variety include the various taxonomic units of animals and plants such as phylum, class, order, family, genus, and species.

With regard to the provisions concerning human embryonic stem cells and human embryos, they are substantially consistent with the practice in China although it may be argued that it is the duty of the public health administration and not the patent office to issue such a law to exclude them so as to adapt to the rapid changes of social ethics. That is to say, even if Dr. Hwang's research were true, his cloned human embryonic stem cells could not be patented in China. The provisions on the animal variety and plant variety also conform to the practice in China. This differs from the European approach. In Europe, to protect animal and plant varieties, the European Patent Office oddly defines the concept of animal and plant varieties to not include the various taxonomic units. Such an explanation is illogical.

(The article was written in Chinese, the English version is the translation.)

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