WIPO National Workshop on Search and Examination
of Inventions related to Genetic Resources
Manila, Philippines, May 20 to 24, 2019

OVERVIEW: KIPO's Best Practices in Examining Inventions Related to Biosequences

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CLAIMS

Claims must describe the matter for which protection is sought.

Claim must define the invention clearly and concisely. [Art 42.4(ii) KPA] (Clarity requirement)

Claim must be supported by the detailed description of the invention. [Art 42.4(i) KPA]

Genes

Genes, or DNA fragments should be worded using nucleotide sequence; and the assessment of novelty is realized based on the structure (nucleotide sequence)

Claimed:

A gene *abc* isolated from plant A consisting of a nucleotide sequence of SEQ ID NO:1

Use Claims

EPO:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Guidelines for Examination in the European Patent Office

The effect of the different claim formulations on patentability is summarised in the table below:

Examples			
#	Claim	Patentable?	Article
A	Use of product X for the treatment of asthma	No	53(c)
B	1. Product X for use as a medicament [X known as e.g. herbicide] 2. Product according to claim 1 for use in the treatment of asthma	Yes (even if X is a known product, but its use in medicine is not known) Yes	54(4)
C	Product X for use in the treatment of cancer*	Yes (even if case B is prior art, provided that such a claim is inventive over B and any other prior art)	54(5)
D	Product X for use in the treatment of leukaemia*	Yes (even if cases B and C are prior art, provided that D is inventive over B and C and any other prior art because leukaemia is a specific type of cancer)	54(5)

* Note: The corresponding Swiss-type claims for cases C and D (required under EPC 1973) would be "The use of Product X for the manufacture of a medicament for the treatment of cancer/leukaemia".

KIPO: X O

http://documents.epo.org/projects/babylon/eponet.nsf/0/2A358516CE34385CC125833700498332/$File/guidelines_for_examination_2018_hyperlinked_en.pdf

Claim Interpretation

Genes for use in ~ → Genes

Proteins for use in ~ → Proteins

Claimed: *A polypeptide of SEQ. ID NO. 1* for use in the treatment of disease Y

The claims should be worded as "A composition for ~".

Claimed:

A pharmaceutical composition comprising polypeptide of SEQ. ID NO. 1 for *treating disease Y*

Claim Interpretation

An invention related to a medical use of a compound having inhibitory activity against a gene or protein, should be worded **by its medical effectiveness** such as diagnosis, treatment or prevention of a disease

Claimed:

A composition for *treating disease A*, comprising a siRNA to gene x

A composition for *treating disease A*, comprising an antibody to protein X

? A pharmaceutical composition comprising polypeptide of SEQ. ID NO. 1 for *inhibiting GAVE8 signal transmission activation*

Claim Interpretation

Gene x and protein X having increased expression specifically for a disease A

Claimed:

A composition for detection of disease A, comprising a probe that binds to gene x

A composition for detection of disease A, comprising an antibody that binds specifically to protein X

Protein Variants

Variant of protein A having better activity X than protein A

Claimed:

A protein variant of protein A, wherein Ala is substituted to His at 90th position of an amino acid sequence of SEQ ID NO:1

When using expressions such as deletion, substitution, or addition, respective positions and contents should be written clearly in the claims.

Variants having deletion, substitution, or addition should be supported by the description in a detailed, sufficient way

Protein Variants

Claimed:

A protein A, wherein the amino acid of the position 25, 30, 89 or 251 to 254 is substituted with a hydrophobic amino acid

In this case, the substitution is a hydrophobic amino acid, and the substitution of all hydrophobic amino acids should be sufficiently supported by the detailed description.

Protein Variants

Claimed:

1. A protein X of (a) or (b) as follows:
   (a) An amino acid sequence of SEQ ID NO. 1;
   (b) A mutant having over 95% homology with the sequence of SEQ ID NO. 1, and the activity of enzyme E.

Protein X has the activity of enzyme E. In the case of (b), the expression ‘over 95% homology’ should be supported by the detailed description, which provides a concrete example with respect to a mutant having 95% homology.

SNP of gene y in disease A

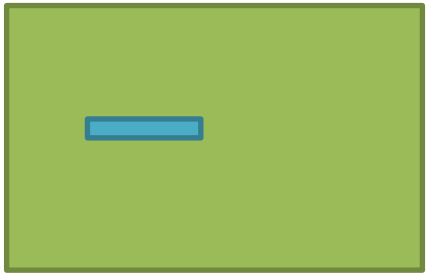
Claimed:

1. A method of analyzing a genotype of gene y for Koreans, comprising a step of amplifying nucleotide sequence of SEQ ID NO:1 of gene y, wherein the base pair at the position 185 of gene y is substituted from C to G, for providing necessary information for diagnosis of disease A

An invention related to SNPs, a nucleotide sequence should be identified by a SEQ ID NO., and α is substituted to β at a certain position (base pair at the position OO) of the nucleotide sequence should be identified.

Primers

For a known gene, the primers for amplifying that gene lack inventive step.



In order to meet the inventive step, an unexpected effect and function of said primers should be identified.

Protein fragment

Protein fragment a of full length protein A, responsible for activity X

Claimed:

1. A polypeptide consisting of an amino acid sequence of SEQ ID NO:1

Detailed activity data of the polypeptide consisting of an amino acid sequence of SEQ ID NO:1 should be disclosed in the description (examples)
- Same (or improved) activity should be proven using the polypeptide compared with the full length protein

Antibodies

Having better inhibitory effects against Ag A than existing Abs

- ✓ Describe: how to obtain (prepare) the antigen, how to prepare Ab using Ag, how to prepare cells producing Abs (hybridoma, KCTC OOOOp)
- ✓ Identify hybridoma that produces selected monoclonal Abs, and sequence analysis of heavy and light chain regions of monoclonal Abs, especially complementary determining region (CDR)
- ✓ Proof of the effectiveness of Ab of the invention through identifying binding affinity to Ag, comparing with Abs of prior art

Claimed:

1. An antibody comprising:
   a heavy chain CDR1 sequence consisting of SEQ ID NO:1;
   a heavy chain CDR2 sequence consisting of SEQ ID NO:2;
   a heavy chain CDR3 sequence consisting of SEQ ID NO:3; and
   a light chain CDR1 sequence consisting of SEQ ID NO:4;
   a light chain CDR2 sequence consisting of SEQ ID NO:5;
   a light chain CDR3 sequence consisting of SEQ ID NO:6;
2. The antibody of claim 1, wherein the antibody comprises a heavy chain variable region consisting of SEQ ID NO:7; and a light chain variable region consisting of SEQ ID NO:8

Industrial Applicability – Utility

As to an invention of genes, DNA fragments, antisense, vectors, recombinant vectors, transformants, fused cells, proteins, recombinant proteins, monoclonal antibodies, etc., if the specific, virtual and reliable utility is not described, or the utility thereof cannot be inferred, the invention is not recognized as an industrially applicable invention as set forth in the provisions of Article 29(1) of KPA.

As to an invention of a **DNA fragment**, the description of the DNA fragment as only a probe to be used to obtain full-length DNA is not regarded as having utility. However, when the invention has a concrete description, such as use as a probe to diagnose a specific disease or encode a specific protein, the invention is regarded as having utility.

As to an invention of **SNP** (Single Nucleotide Polymorphism), when the invention is experimentally shown to be useful as a diagnostic medicine, etc., the invention is considered to have utility.

Industrial Applicability – Utility

As to an invention of **full-length cDNA**, when a gene of specific protein is deduced by the result of a homology search through a known D/B, the **invention is not regarded as having utility**. However, when the deduction can be objectively recognized as a gene of a specific protein (in the case where homology with the specific protein is high and homology with the protein having second similarity is low), the invention is regarded as having utility. For example, in the case where homology with a specific protein is over 90% and homology with a second protein also having similarity is lower than 50%, the invention is considered to have utility.

As to an invention of **a protein**, when the invention describes only the sequence without the physical, chemical or biological properties of the protein, the **invention is not considered to have utility**.

Enablement Requirement

- The detailed description of the invention shall *disclose the pharmacologic effect* to support the medical use at the time of filing.

Unless special conditions exist such as where pharmacological mechanisms of use inventions on medicine with requirement of disclosure of medicinal effects are clearly disclosed prior to the filing, only if trial examples containing *pharmacological data or detailed description of medical effects* in particular materials are present, such use inventions on medicine shall be deemed *to be complete and meet the description requirement of the specification*. (Supreme Court, 2006. 2. 23 Ruling, 2004 Hu 2444 Decision)

Industrial Applicability

A method for treating and diagnosing the human body is not recognized to be an industrially applicable invention under the provisions of Article 29(1) KPA.

A method invention, such as a gene treatment method targeting the human body, falls under the medical act, and accordingly, is not recognized as being industrially applicable. However, when the substance used for treatment and diagnosis is described as claims of medicine specifying medical effect, the invention is recognized as having utility.

Industrial Applicability

Not industrially applicable

1. Method of surgery
2. Method of treatment
3. Method of diagnosis
4. Method comprising medical behavior and non-medical behavior
5. Method comprising both treatment and non-treatment (ex. cosmetic) effects

Examples:

1. Method of surgery to remove cataract
2. Method of hemodialysis
3. Method of diagnosing lung state through X-ray
4. Method to detect protein A comprising steps of obtaining a sample from human, and reacting it with antibody (when extracting a sample is realized by surgery)
5. Method of transplanting stem cells into the bald area, the cells obtained by selecting cord blood that matches six HLA genes with the patient

Industrial Applicability

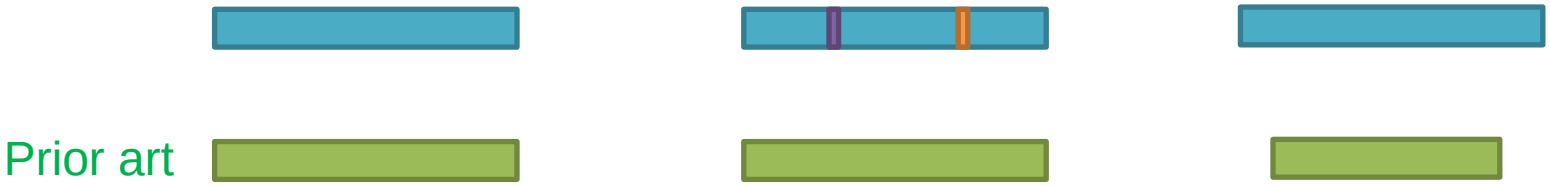
Industrially applicable

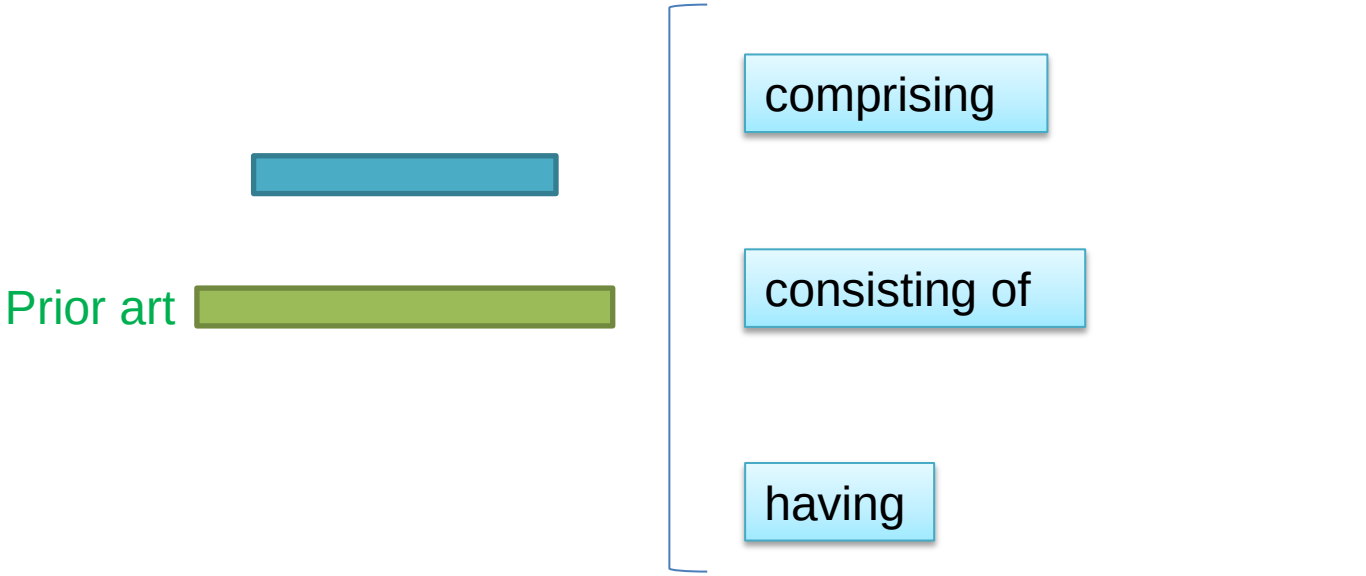
1. Method to treat, diagnose or prevent disease of mammals, or promote their growth except humans (restricted to animals)
2. Method related to diagnosis without comprising clinical judgment
3. Method related to medical behavior by medical apparatus
4. Method to processing what is extracted from human body (blood, urine, skin, hair, etc.)
5. Method to realize physicochemical measurements or analysis

Examples:

1. Method of treatment for mammals except humans
2. Method to detect cancer marker A by using Ag-Ab reaction from a sample of a patient for providing necessary information about colon cancer diagnosis
3. Method to place electrode to measure electrocardiogram
4. Method of culturing tumor cells isolated from tissue sample
5. Method to measure blood glucose level from the extracted blood

DNA/PEPTIDE Fragment

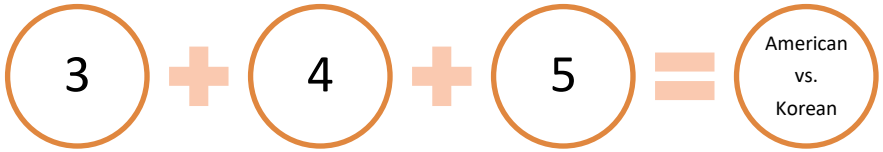




Sample Case1

Claims:

1. A PNA probe corresponding to SEQ ID: NO. 3 for distinguishing the type of ginseng
2. A PNA probe corresponding to SEQ ID: NO. 4 for distinguishing the type of ginseng
3. A PNA probe corresponding to SEQ ID: NO. 5 for distinguishing the type of ginseng



Claims:

1. A biochip comprising PNA probe 3, PNA probe 4 and PNA probe 5 corresponding to SEQ ID: NOs. 3, 4 and 5, respectively, for distinguishing between Korean ginseng and American ginseng

Sample Case 2

Claim 1:

1. A polymer-siRNA delivery carrier with the following structure in which a polymer (A) and a siRNA (B) are connected by using charge interaction and biodegradable covalent bonding at the same time:
A-B
wherein, “A” is a polymer having positive charge and functional group, and “B” is a siRNA having a functional group at one end or both ends thereof.

Thank You !