

***Trilateral Project 24.1***  
***Biotechnology Comparative Study***  
***on Biotechnology Patent Practices Comparative Study***  
***Report***  
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## **Foreword**

In the beginning, the JPO notices that the JPO explains relevant provisions and practices mainly on the basis of 1994-Revised Patent Law (applicable to applications filed on and after 1995.7.1.)

## **1. Requirements for Disclosure and Claims General**

The three Offices explain the reasons for rejection.

The USPTO explains, based on the Patent Act, Sections 101, 102, 103 and 112.

The EPO shows all the reasons, including the substantive requirements for disclosure and claims. On the other hand, the JPO explains in detail the requirements for disclosure and claims.

### **1.1 Claims**

#### **1.1.1 Clarity of Claims**

##### **1.1.1.1 General rules**

(1) Is it allowed that a claim is defined only by the objective to be reached ?

If they can, how should such a claim be interpreted ?

Should such a claim be called a "single-means" claim ?

The three Offices point out that a claim defined only by the objective to be reached has problems in the light of clarity of claims and of enabling disclosure.

The USPTO states that a claim may not be defined only by the objective to be reached because it would not be commensurate in scope with the enabling disclosure.

The EPO states that the scope of a claim must be clearly and unambiguously defined and in general, claims which attempt to define the invention by a result to be achieved are not allowed, in particular if they only amount to claiming the underlying problem, in other words the result to be achieved, however, claims worded in terms of functional features may be allowed if the invention either can only be defined in such terms or cannot otherwise be defined more precisely without unduly restricting the scope of the claims and if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description or known to the person skilled in the art and which do not require undue experimentation.

In the JPO, a patent application shall not be rejected on the ground of the lack of clarity of claims merely because a claim includes a statement defining a product only by the objective to be reached, however, it is the lack of clarity of claims, if a claimed invention cannot be clearly identified by a skilled person as a result of such claim statements, particularly, if the extent of the claimed invention is unclear to a skilled person even taking into account the specification, drawings and common general knowledge as of the filing.

(2) Is it allowed to use a result to be achieved as one of the elements (technical features) of the claimed

invention in combination with the other elements (technical features) ?

Does the judgement depend on whether such an element is known to the public as of filing ?

Should such claim be called a "means-plus-function" claim ?

The three Offices allow to use a result to be achieved as one of the elements (technical features) of the claimed invention in combination with the other elements (technical features), however, the EPO allows such a claim only on the specific conditions as

mentioned above 1.1.1.1(1) if such a element is the essential one.

(3) Is it allowed to refer to drawings or tables (including DNA sequence, amino acid sequence, cleavage map of the DNA, etc.) in the claims ?

The USPTO explains that a reference is allowed, as long as the meaning of the claims is definite. On the other hand, in the EPO, claims shall not, except where absolutely necessary, rely on the references to the description or drawings. An exceptional case is a claim for a DNA or protein; in these cases a reference to a drawing or table containing the DNA sequence, amino acid sequence or restriction map of the DNA, respectively, is allowed.

This handling is equal to that of the JPO on the basis of 1987-Revised Law, but the JPO explains that a reference is available when it leaves the claimed invention clear and concise under the 1994-Revised Law.

## **1.1.1.2 Details**

### **1.1.1.2.1 Structural gene**

(1) Where a claimed invention concerning structural gene is not characterized by its DNA sequence but only by its function, is the claim specified clearly ?

ex. A DNA isolate consisting essentially of a DNA sequence encoding human protein X.

(Notes) The word "protein X" stands for a certain protein, like immune IFN, t-PA, etc. In the following, the word "protein X" is used as the same meaning.

Is such a claim described above regarded as a "means-plus-function" claim or as a "single-means" claim?

The practices in the three Offices are common in that a claim directed to a structural gene characterized only by its function (encoding "protein X") is allowed provided the human "protein X" is clearly defined in the specification and is sufficiently characterized by structural features.

Concerning the terminology of "means-plus-function" and "single-means", the USPTO states that such a claim is not normally labeled as a kind of "means" claim. The EPO mentions, in the prior questionnaire, such a terminology does not apply in the practice. The JPO explains that the claimed invention should be denied its novelty if any one of the every possible means for achieving the objective (result) stated in the claim is publicly known, and there is no distinction in the claim construction between so-called "single-means" and "means-plus-function" in this sense.

(2) Where a DNA is characterized by "having some extent of identity to a DNA sequence" in a claim, is the claim specified clearly ?

ex. A DNA sequence encoding protein X, said DNA sequence having at least 40% identity to the DNA sequence in Fig. 1.

(Notes) Suppose that a specific DNA/amino acid sequence is described in "Fig. 1". In the following, "Fig. 1" is used as the same meaning.

The three Offices, in principle, agree that it is clear if an appropriate definition of "identity" (homology) is provided in the specification, however, the EPO states that the limit of "at least 40% identity to the DNA sequence in Fig. 1" is too low to ensure that the protein encoded by the degenerated DNA sequences remains the same and the JPO states that enablement requirement should be examined because the claimed DNA having identity (homology) with the specific DNA may be unlikely to have similar activity as the specific DNA.

(3) What are the requirements for specifying a claim in which a DNA is characterized by "hybridizing" to a specific DNA sequence ?

For example, i) a DNA sequence has to be a naturally-occurring product, ii) the condition of hybridization must be defined, iii) the source of a DNA must be specified (ex. human being, mouse etc.)

ex. A DNA sequence encoding human protein X, said DNA sequence being selected from the groups

consisting of:

- a) the DNA sequence set out in Fig. 1 or its complementary strand; and
- b) naturally obtainable DNA sequence which hybridizes under stringent conditions to the DNA sequence defined in a).

There are some differences in the answers of the three Offices.

In the USPTO, for the purposes of clarity, there are no requirements for specifying the term "hybridizes", and the term "hybridizes" is itself a term of art which is clear though broad.

The EPO answers that it is possible in a claim to characterize a DNA sequence by "hybridizing" to a specific DNA sequence only on condition that the hybridization conditions are defined in the claim.

The JPO states that a hybridization claim can be defined by a description containing all the elements listed below as 1) - 3);

- 1) one or more nucleotide sequences defined in, for example, working example
- 2) the phrase of "under stringent conditions" in the claim (the conditions be provided in the detailed description of the invention)
- 3) property or function of encoded protein

(4) What are the requirements for specifying a claim like the following example ?

ex. A DNA encoding a protein which has the function of protein X and which comprises a derivative, by way of amino acid substitution, deletion, addition or insertion of the amino acid sequence set out in Fig.1.

For example, is it necessary to define the number of bases which may be added, deleted or substituted ?

The USPTO answers that definition of the terms substitution, deletion, addition and insertion do not require numerical definition for the purposes of clarity and specificity. However, the USPTO points out that the broadest interpretation of these terms would result in a very broad claim encompassing many DNAs. Moreover, proteins have many functions and the intended function of protein X is not recited possibly making the DNA indefinite.

In contrast, the EPO and the JPO state that an addition/deletion/substitution type claim can be defined with elements 1) - 3);

- 1) one or more nucleotide sequences or amino acid sequences defined in, for example,

working example

2) a clear definition of the term "addition, deletion, substitution," provided that "the sequences added, deleted or

substituted" have a high degree of identity (homology) with the sequences of 1)

3) property or function of encoded protein

(5) Allelic mutant, Derivative, Equivalent, Variant Where a claim states as an "allele or allelic mutant", or a "derivative", or an "equivalent", or a "variant" of a specific DNA sequence, is the claim specified early ?

ex. A DNA sequence encoding human protein X of the amino acid sequence depicted in Fig. 1 hereof or

allele or derivative thereof having the function of human protein X.

Again, there are some differences in the practices in the two Offices (the EPO and the JPO) and these in the USPTO.

In the JPO, it depends on the definition of the terms in a specification whether or not the claim containing the above-mentioned terms is clear. To be judged clear, it is necessary to provide a clear description that the differences between the amino acid sequences of allele or derivative and the standard sequence shown in Fig. 1 are within a certain range.

The EPO states that on condition that a DNA sequence is clearly defined in a claim, the variants etc. of the DNA sequence fulfill the requirements of clarity provided that the variants etc. of said DNA sequence are additionally all defined as encoding proteins which have the same properties as protein X.

On the other hand, the USPTO states that "derivative", "equivalent" and "variant" do not have well recognized, specific meaning in the art of molecular biology and their use as in this question would raise an issue as to specificity. The USPTO states that one would look to the specification and the state of the art to determine the definition of allele or allelic mutant.

### **1.1.1.2.2 Recombinant protein : Protein as obtained by using recombinant DNA technology**

Where claims related to recombinant proteins are described in the same form as the claims of structural genes discussed in 1.1.1.2.1(1) - (5) above, would they be regarded in the same way ? If different judgement is made about those proteins, please discuss in this paragraph.

(1) In case where its amino acid sequence is not described and only its function is described in a claim.

ex. A recombinant protein having the function of human protein X.

(2) In case where a protein is described as "having some extent of identity" to a specific sequence in a claim.

ex. A protein having protein X function and which is encoded by a DNA, said DNA having at least 40% identity to the DNA sequence in Fig. 1.

(3) In case where a protein is characterized by "hybridizing" to a specific sequence.

ex. A protein having protein X function and which is encoded by a DNA sequence, said DNA sequence being selected from the groups consisting of:

a) the DNA sequence set out in Fig. 1 ;and

b) naturally obtainable DNA sequence which hybridizes under stringent conditions to the DNA sequence defined in a).

(4) In case where a protein is characterized by "addition-deletion-substitution".  
ex. A protein having protein X function and which comprises a derivative, by way of amino acid deletion, substitution, insertion, inversion or addition of the amino acid sequence as encoded by the DNA in Fig. 1.

(5) Allelic mutant, Derivative, Equivalent, Variant

ex. Protein X of the amino acid sequence depicted in Fig. 1 hereof or allele or derivative thereof having the function of protein X.

These questions (1) - (5) correspond to the prior questions 1.1.1.2.1(1) - (5).

Concerning (1), the USPTO and the EPO comment that a recombinant protein being defined only by having the function of a certain protein X would lack clarity because a protein has several different functions.

As to (2) - (5), the answers of the two Offices (the EPO and the JPO) are the same as their answers of corresponding questionnaire 1.1.1.2.1(2) - (5); the USPTO gives answers that differ from their answer to the corresponding question 1.1.1.2.2(2), (3) and (5). The differences arise from the recitation of a protein function in the protein claims which is not present in DNA claims 1.1.1.2.1(2) and (3). The USPTO points out that the specification must be consulted to determine the meaning and clarity. The USPTO supplements its explanation for 1.1.1.2.1(2) by pointing out that it is often possible to arrive at different extents of sequence identity between sequences because of many different algorithms for comparing and many different variables in these algorithms.

Is there any difference to define claims between recombinant DNAs and recombinant proteins, in case that structural genes which encode proteins with a biological function are cloned ? If there are some differences, what is the reason for the differences ? For example, is the claim "a DNA encoding a protein X and which comprises a derivative by way of amino acid substitution, deletion, addition or insertion of the amino acid sequence set out in Fig. 1" definite ?

On the contrary, is the claim "a protein which has the function of protein X and which comprises a derivative by way of amino acid substitution, deletion, addition or insertion of amino acid sequence set out in Fig. 1" indefinite ?

If it is indefinite, does it become definite by describing "the function of protein X" more clearly and concretely ?

The EPO and the JPO reply that there are no differences between them.

The USPTO answers that such a claim as "a protein which has the function of protein X and which comprises a derivative ... in Fig. 1" is not clear, because a protein rarely has only one function. However, it may become clear, if the function of protein X is defined precisely.

### **1.1.1.2.3 DNAs, other than structural gene**

(1) Where a claimed invention is directed to a DNA fragment used as a probe for analysis, are those forms of claims described in 1.1.1.2.1(2) - (4) above allowed ? If there are any more suitable words to define DNA fragments, please discuss them in this paragraph.

The three Offices agree, in principle, that a DNA fragment must be clearly defined by technical features, but there are some differences in their answers.

The USPTO explains that a probe claim relating to addition/deletion/substitution would be very difficult to draft because encompassed within the claim are probes which may be specific for a region of the disclosed sequence that is varied.

The EPO emphasizes a precise definition of the fragment/probe length or of the part of the amino acid sequence of the protein or peptide.

The JPO shows the two requirements for being a DNA probe for analysis; 1) it can strictly hybridize with polynucleotides to be detected, 2) it does not hybridize with polynucleotides concerning similar polypeptide, and as a result, enablement requirement is generally considered not to be satisfied in many cases where DNA probes for analysis are specified by homological, hybridization and addition/deletion/substitution sequences.

(2) Where a claimed invention is directed to a regulatory sequence like promoters and so on, are those forms of claims described in 1.1.1.2.1(2) - (4) above allowed ?

If there are any more suitable words to define regulatory sequences, please discuss them in this paragraph.

Again, the three Offices coincide that a regulatory sequence must be clearly defined by technical features.

In particular, the USPTO and the EPO explain the requirements for such a claim, that is, mainly certain extent of identity, hybridization conditions and/or the kind and extent of mutations of the specific DNA sequence.

The JPO shows that the length of a nucleotide sequence corresponding to actual regulatory function in sequence confirmed to possess some regulatory function is extremely shorter than that of structural genes, therefore, it is likely that a DNA defined by identity (homology), hybridization, or addition/deletion/substitution relating to a regulatory sequence would lose the function of the original sequence.

#### **1.1.1.2.4 Transformant, Fused cell**

(1) Where the word "transformant" implies not only cell cultures and microorganisms but also plants and animals themselves, is a claim using the word "transformant" specified clearly ?

ex. The claim is, "A transformant transformed with a DNA sequence encoding for protein X.", and in the description of the invention defines "transformant" to include cell cultures, microorganisms, animals themselves and plants themselves.

The three Offices agree that the term "transformant" itself is not unclear.

In addition, the USPTO and the EPO point out that "transformant" may not be acceptable if the definition in the specification would be considered repugnant to the normally accepted usage of the term. Furthermore, the two Offices notice that a broad interpretation to include humans would be unacceptable.

(2) Where the claimed invention is directed to a fused cell which produces a monoclonal antibody, what is the element necessary in the claim other than the monoclonal antibody itself ? (ex. name of the used host cell or parental cell etc.)

The USPTO answers that it may be specified with a deposit designation.

Concerning the specific hybridoma, the similar answer is revealed by the EPO and the JPO. The two Offices, though, explain that a broad claim directed to a fused cell can be characterized by a combination of parent cells, function/properties and production (produced monoclonal antibody). And the USPTO concurs with the EPO and the JPO for such a broad claim.

## **1.1.2 Relationship between Claims and Description of the Invention [ex. Support in description of the invention (Relationship between working examples and claims), Adequate written Description, etc.]**

Please discuss those issues mentioned below in "1.2.1 Enablement Requirement" in this paragraph, if the USPTO or the EPO finds it more proper to handle those issues as a matter of "support" or "adequate written description" for the invention described in the claims.

(For example, if those issues mentioned below are considered under EPC Article 84 rather than EPC Article 83, it might be reasonable to handle them in this paragraph.) The different thinking around this question is recognized between the EPO and the JPO.

In the JPO, it is enough to satisfy a requirement for the Patent Law Section 36(6)(i) that the matter corresponding to what is claimed is formally written in the detailed description of the invention. Consequently, it is usually discussed as the matter of "enablement requirement."

On the other hand, the EPO explains that an objection of lack of support under Article 84 EPC can often also be considered as an objection of insufficient disclosure under Article 83 EPC.

The USPTO gives answers that the specification must provide both a written description of the invention and sufficient enablement to practice the invention as claimed. These are separate and distinct requirements of the statute 35 U.S.C.112, first paragraph.

## **1.2 Description of the invention**

### **1.2.1 Enablement Requirement (Adequacy of Disclosure)**

#### **1.2.1.1 General rules**

The report "Consolidated Comparative Study of Patent Practices in the Field of Biotechnology Related Mainly to Microbiological Inventions"(1990.1) of Project 12.3 and the report "Comparative Study Report on Requirements for Disclosure and Claims"(1990) of Project 12.6 have been made. Considering these reports, please explain the following items.

(1) Please explain the examining practice related to "Enablement Requirement (Adequacy of Disclosure)" in detail.

For example, please refer to "how to make" and "how to use".

The three Offices coincide that enough or sufficient information is needed to carry out the claimed invention by a person skilled in the art, without undue experimentation and using his common general knowledge as of the filing.

In addition, the EPO states that the description must disclose any feature essential for carrying out the invention in sufficient detail to render it obvious to the skilled person how to put the invention into practice. Also, the JPO explains that normally one or more representative embodiments or working examples are necessary in the case of

inventions in technical fields where it is generally difficult to infer how to make and use a product on the basis of its structure.

(2) Is there difference in the definition (level) of the "person skilled in the art" between the assessing inventive step and the assessing sufficiency of description ? The three Offices show that there may be no practical difference about the term "person skilled in the art" itself, between the assessing inventive step and the assessing sufficiency of description.

The three Offices agree that the range of knowledge is limited only to the "common general knowledge" as of the filing, not to all the "state of the art" as of the filing including common general knowledge for assessing sufficiency of description.

(3) In determining whether claimed invention not accompanied by sufficient description in the specification can be carried out by a person skilled in the art, should an examiner take into consideration either the common general knowledge (such as well-known or commonly used art) or all the relevant documents in the state of the art ?

In general, an examiner should take into consideration the "common general knowledge" in all the three Offices.

The EPO notices that patent specifications may exceptionally be considered as forming part of common general knowledge in a field of, for example, biotechnology, which field is so new that the relevant technical knowledge is not yet available from textbooks.

(4) If the applicant presents the written argument (or the certificate on the result of experiment) which includes the explanation of how to make and how to use without amending the specification, may the reason for rejection related to the enablement requirement be overcome ? Is it possible to take into consideration those relevant documents which were published after the filing date ?

The three Offices give the same answer to this question, that is, the reasons for rejection related to the enablement requirement shall be overcome if the examiner determines that the claimed invention can be carried out by a person skilled in the art based on what is described in the specification and common general knowledge as of the filing, when the applicant presents literature that is clearly establishing the common general knowledge as of the filing in a written argument. The literature published after the filing may be also available if the contents of this literature clearly represent the common general knowledge as of the filing.

(5) What kind of factors may be taken into account in determining whether the experimentation required is undue (or unreasonable) ?

The USPTO and the JPO point out the same several factors listed below;

- quantity of experimentation needed
- amount of direction or guidance given in the specification
- the presence or absence of working examples (shown only by the USPTO)
- the nature of the invention
- state of the prior art
- relative skill levels present in the technical area
- predictability of that particular art
- the breadth of the claims

The EPO explains that the sufficiency requirement would not be fulfilled if the successful performance of the invention is dependent on chance and is achieved in a totally unreliable way; however if repeated success is assured even though accompanied by a proportion of failures, this would not be considered as undue experimentation.

(6) Which one has the burden of giving reasons why the specification is (not) enabling, an examiner or an applicant ?

The practices of the three Offices are common in that the initial burden of pointing out the reason of rejection is on the examiner. However, though the JPO and the EPO find that the burden of proof (the burden of persuasion) is finally on the applicant throughout prosecution, the USPTO must always shoulder the burden of proving that the specification is not enabled.

(7) Where there are well-founded reasons to believe that a skilled person would not be able to extend teaching of the description to the whole of the field claimed, what kind of evidences should an examiner prepare necessarily ?

Should such reasons be supported by a published document ?

Please explain other examination practices related to "well-founded reasons" in detail, if any.

The USPTO explains that unpredictability in the art and lack of working examples are important in questioning whether the invention is enabled throughout the scope of the claim.

The EPO gives two examples that 1) a specific microorganism isolated by chance and not deposited is being claimed or 2) common general knowledge suggests a claimed invention would not be repeatable.

According to the answer of the JPO, among the concrete reasons is the reasoning that a skilled person would be unable to extend the particular enabling description in the detailed description of the invention to the whole of the field within the extent (or the metes and bounds) of the claimed invention.

Furthermore, the three Offices mention that the reasons of rejection should preferably be supported by reference documents.

(8) Where there was no variant of means to solve the problems in a claim other than the only one means used in the working example as of filing, should functional expression be accepted taking into account the other later developed means to achieve the same effect ?

The answers of the EPO and the JPO to this question are similar to the question 1.1.1.1(1).

In particular, the JPO states that, with respect to an application having a claim defined by a result to be achieved and a disclosure of only one specific means to achieve the result, the enablement requirement is judged regardless of the existence or absence of other later developed means.

On the other hand, the EPO points out that a claim may be allowed covering all means later developed if the invention is major one opening up a new field and the teaching of the invention leads the later development.

Also, the JPO shows that inventive step of the claimed invention which defines a product solely by a result to be achieved should be denied when the result to be achieved is a well-known technical problem and a certain product to be defined by the result is either known to or easy-to-invent to a person skilled in the art as of the filing,

unless otherwise inventive step can be positively inferred by other facts, even if a specific means to solve the technical problem is not known as of the filing. The USPTO states that such claims reciting means plus function are authorized, if the claim is drawn to a combination of elements.

### **1.2.1.2 Details**

- (1) The claimed invention is
- (a) a recombinant vector,
  - (b) a process for producing a recombinant vector,
  - (c) a transformant,
  - (d) a process for producing a transformant,
  - (e) a process for producing a recombinant protein X, or,
  - (f) a recombinant protein X.

In the description of the invention, there is a working example of cloning cDNA encoding protein X, but there is no working examples of these inventions themselves. In this case, does this claimed invention (a) - (f) mentioned above meet the enablement requirement respectively ?

The USPTO suggests that it is difficult for the USPTO to definitively determine enablement for the proposed working example and provide specific answers to the questions exemplifying (a) - (f), however, if the description is reasonably adequate to allow one skilled in the art to produce the protein via use of the cDNA as indicated, (a) - (f) would be enabled.

The EPO points out that claims to the subject-matter of (a) - (f) would appear to be enabled, supposing that the actual invention of the application is to be seen in the cloning of the cDNA is sufficiently disclosed in the application. The JPO notices that in case where a person skilled in the art needs undue experimentation in order to express the structural gene and to make the corresponding protein without loss of the original activity as a mature product and the claimed invention which have no corresponding working example would not meet the enablement requirement.

- (2) In the description of the invention, there is a working example of producing only one kind of transformant (ex. E. coli).

Where a claimed invention contains any other kind of transformants than E. coli, does this claimed invention meet the enablement requirement ?

And if this claimed transformant obviously contains an animal or a plant, does this claimed invention meet the enablement requirement ?

The three Offices agree that the answer to this question depends on the case.

As to an animal or a plant, the USPTO and the JPO point out there may be a well-founded reason that transformants in hosts other than the host used in the working example is non-enabling. On the other hand, the EPO states the same criteria as that of microorganism would apply in the case of animals or plants.

- (3) The claimed DNA is characterized by the term "hybridize" (ex. A DNA sequence hybridizing to the DNA sequence X and encoding a polypeptide having the biological activity x).

Where the original cDNA sequence (the DNA sequence X) is disclosed in the description of the invention, while there is no working examples how to clone allelic mutants by way of hybridization, does this claimed invention meet the enablement requirement ?

If the claim contains not only natural-occurring but also artificial DNA, does this claimed invention meet the enablement requirement ?

The USPTO's answer seems to be different from those of the other two Offices. According to the USPTO's answer, the breadth of the claim in the example does include more DNA embodiments than allelic mutants, and the necessary analysis requires an assessment of the adequacy of the description in the specification as to the means of identification of "biological activity X".

On the other hand, the other two Offices reply affirmatively, since it is within common general knowledge to clone other similar DNAs by way of hybridization (the EPO), or the hybridization technology was developed some 20 years ago and it has been used in the relevant field of technology since 1980 as a common method in order to obtain allelic mutants (the JPO).

As to artificial DNA, though, there seems to be different opinions between the EPO and the JPO; the EPO thinks there is no difference whether the DNA is natural or artificial. On the other hand, the JPO thinks many types of artificial DNA sequences, having low identity (homology), are possible to hybridize to the DNA sequence X even under stringent condition.

(4) The claimed DNA is characterized by the term "substitution, deletion, addition or insertion" (ex. A DNA sequence produced by way of nucleotide substitution, deletion, addition or insertion of the DNA sequence X).

Where the original DNA sequence (the DNA sequence X) is disclosed in the description of the invention, while there is no working examples how to produce derivatives by way of substitution, deletion, addition or insertion of nucleotides, does this claimed invention meet the enablement requirement ?

Where the claimed sequence is very short (ex. A DNA sequence coding for the epitope of antigen), does this claimed invention meet the enablement requirement ? The USPTO suggests that a description may be adequate if the description contains adequate guidance as to what compounds are envisioned and how to make such compounds.

The EPO replies that it is within ordinary skill in the art to obtain DNA sequences which are distinguished from a given DNA sequence X by way of substitution, deletion, addition etc.; and this would also apply to very short DNA.

The first half of the answer given by the JPO is similar to that of the EPO; the enablement requirement is generally satisfied without concrete disclosure such as a working example, provided that the application is filed after common technical knowledge was established with regard to the method of making an addition, deletion and substitution to a nucleotide sequence coding a natural-occurring protein without losing the proteins functions and properties. When the claimed invention is related to

derivatives of a short sequence, however, it is very likely that the function would be lost through a modification of nucleotides.

(5) The claimed invention concerns any several contiguous amino acid fragments of a pathogenic viral antigen. (ex. A polypeptide in substantially isolated form comprising a contiguous sequence of at least 8 amino acids encoded by the genome of X virus and comprising an antigenic determinant, wherein X virus is characterized by 940 amino acid sequence in Fig. 1.)

What description meets the enablement requirement ?

The USPTO points that it depends on whether or not the entire polypeptide sequence is disclosed and what "biological activity" is claimed.

The JPO also explains that its distinctiveness is extremely important and such conditions as immunogenicity are required in addition to the above-mentioned conditions with regard to vaccines.

In contrast, the EPO states that this would fulfil the enablement requirement because such polypeptides could be obtained by a person skilled in the art.

(6) The claimed DNA is characterized by its identity with a certain nucleotide sequence. (ex. A DNA sequence having at least x% identity to a DNA sequence in Fig. 1)

Even if its rate is low (ex. x=40%), does this claimed invention meet the enablement requirement ?

The USPTO states that there would be no problem "making" but there might be an issue as to "using" the sequence. The JPO states that the enablement requirement would not be met because such a claim clearly includes DNAs which do not satisfy the requirement for utility.

On the other hand, the EPO only replies that the enablement requirement would in principle be met.

(6') If the claimed DNA is characterized only by its identity with a certain nucleotide sequence, is the enablement requirement met or not ?

If the claimed DNA is characterized by its identity with a certain nucleotide sequence and is defined by its function, is the enablement requirement met even if the rate of identity is low ?

There are some differences among answers of the three Offices.

The USPTO replies that it depends on what the invention actually is, and comments that it is important to permit applicants to claim DNAs that may have only a limited amount of identity with a specific sequence. The USPTO explains that even such low identity DNAs could, for example, still code for the same protein as the specific sequence.

Because of the underlying factual determinations necessary to determine enablement, each application must be reviewed on its facts and few per se rules can be articulated.

The EPO replies that the enablement requirement would be met in the both cases.

On the other hand, the JPO states that in the both cases the enablement requirement would not be met.

(7) The claimed DNA is not characterized by its nucleotide sequence but only by its function. (ex. A DNA sequence encoding protein X)

Does this claimed invention meet the enablement requirement ?

The answers of the three Offices to this question are similar to the prior cases 1.1.1.1(1), 1.1.1.2.1(1) and 1.1.1.2.2(1).

(8) The claimed DNA is characterized neither by its origin nor by its nucleotide sequence.

In the description of the invention, there is only one working example of cloning cDNA from a specific origin (ex. mouse).

Where the claim contains DNA prepared from any other origins (ex. human) than mouse, does this claimed invention meet the enablement requirement ?

The three Offices have the similar opinion; namely, "it would require an analysis of both the specification description and the state of the art at the time of filing" (the USPTO), "if a person skilled in the art could obtain the DNA from other origins without exerting inventive skill" (the EPO) and "taking into account the common general knowledge as of the filing" (the JPO).

(9) The claimed invention is a monoclonal antibody to a novel protein.

(ex. A monoclonal antibody which specifically binds to protein X.)

Where there is no working example of preparing a monoclonal antibody to the novel protein in the description of the invention, what description meets the enablement requirement ?

If the immunogenicity of the protein is recognized, does this claimed invention meet the enablement requirement ?

If so, can its immunogenicity be recognized with descriptions as follows ? :

(a) The molecular weight of the novel protein is more than 10kDa.

(b) With regard to inventions for diagnostic use, the novel protein is not in human being originally.

(c) An antibody has already been prepared by an immunogenic protein closely similar to the above novel protein.

(10) The claimed invention is a certain monoclonal antibody.

In the case where there is a working example of producing the monoclonal antibody in the description of the invention, but the hybridoma producing the monoclonal antibody is not deposited, what description meets the enablement requirement ?

There are some differences among answers of the three Offices.

The USPTO explains there is no general rule, and each application must be separately considered based on the disclosure provided and the particular antibody claimed.

On the other hand, the EPO suggests it is well-known that by use of the classical fusion technique of Kohler and Milstein, monoclonal antibodies against a predetermined antigen can be routinely obtained, i.e. without performing inventive skill;

no problems as to the enablement requirement would appear to arise in cases (a) - (c) of the question (9). On this point, the JPO states about the immunogenicity that (a) and (b) themselves are insufficient and (c) is enough.

As to specific monoclonal antibodies, however, the three Offices answer the similar way that the deposition of cells is necessary in principle.

(9) EPO JPO USPTO

(10) EPO JPO USPTO

### **1.2.2 Deposition**

(1) With regard to microorganisms that are used for inventions, where it is not clear whether they are publicly available or not, how do you deal with such cases as follows ?

The EPO, the USPTO and the JPO reveal the several requirements in the case that a microorganism is necessary in order to carry out the invention.

(a) The application comprises the germ or virus which the depository institutions reject to store because of its danger.

There are some differences among answers of the three Offices.

The USPTO explains that it has never encountered an organism that no recognized depository would store because of the organism's danger.

The EPO states that the enablement requirement would not be met in this case.

The JPO states that the enablement requirement would be met, provided that such germs or viruses which are rejected to store because of its danger are stored by the applicants, and these microorganisms can be freely furnished throughout the patent term.

(b) The microorganisms are not deposited, but the applicant describes in the specification that he may furnish them.

The USPTO explains it is necessary for the applicant to make a clear assurance that the microorganism will be deposited on or before payment of the Issue Fee.

The EPO only mentions that the microorganism would clearly not be available to the public.

In the JPO, deposit with depository institutions for the purpose of patent procedure before the filing, is needed to meet the enablement requirement, in principle.

(c) The microorganisms are deposited to universities or research institutions unrelated to the patent system and the catalogs of these deposited microorganisms are published. The EPO states that the microorganisms are not publicly available in this case.

The USPTO states that the microorganisms may or may not be publicly available. The USPTO averred that certain organisms are so well known in the art and so widely available that their access is probable throughout the life of the patent.

The JPO states that the enablement requirement is met, where in the case that the microorganisms relating to the patent application are described in the published

catalogs and it is confirmed before the filing that the microorganisms can be freely furnished.

(d) The published documents, in which the microorganisms are referred, are cited in the specification and the author states that he is ready to furnish them to anyone in the documents.

The EPO states that microorganisms are not publicly available in this case. The USPTO agrees with the EPO and points out that although the organism may be "publicly available" in the lay sense, they are not publicly available in the technical sense of patent law required to satisfy the enablement requirement.

The JPO states that the enablement requirement is met, where in the case that the microorganisms relating to the patent application are identical to the microorganisms described in the published documents and it is confirmed before the filing that the microorganisms can be freely furnished.

(2) In the cases (a) - (d), how can the applicant prove that the microorganisms are available except for submitting catalogs or published documents ?

Declaration evidence and exhibits (letters or other documentation from people who have had access to the Biological Material) that support the declaration (the USPTO), or presentation of catalog listing the commercial products in case that the microorganism was available on the market as commercial products before an application is filed (the JPO) is showed as examples.

On the other hand, the EPO states that no other way can be seen.

(3) Is there any domestic depository institution for the purposes of patent procedure besides International depository authorities ?

The USPTO has not recognized any domestic depository institution other than IDAs. On the contrary, the EPO has bilateral agreements with a few Depository Authorities (listed in the Official Journal) and the JPO has the Patent Microorganisms Depository of the National Institute of Bioscience and Human-Technology, Agency of Industrial Science and Technology, the Ministry of International Trade and Industry as a domestic depository institution.

## **2. Patentability**

### **2.1 Industrial Applicability (Utility)**

Does the invention of human genome DNA/cDNA/cDNA library meet the requirement of industrial applicability in each below case (1) - (4) ?  
(A claimed invention is the underlined DNA)

In front of the particular answers, the three Offices discuss the general thinking.

The USPTO, who suggests that the concept of "industrial applicability" is applied only to those applications filed under the PCT in the International Stage and National Stage applications are examined based on 35 U.S.C. Section 101 and 112(1), explains that the "industrial applicability" is not coextensive with the utility requirements.

The EPO explains that "industry" is understood in its broad sense as including any physical activity of "technical character" and it is necessary for the applicability that the invention can really be manufactured and is sufficiently disclosed; medical treatment per se is excluded from industrial application.

The JPO shows that it must be industrially applicable for an invention to be patentable. In the JPO, a "product can be used" is interpreted as meaning that a product can be used in an industrially applicable way; and this should be shown in the detailed description of the invention.

(1) The specification discloses only that the cDNA library has been constructed from mRNA extracted from an important organ (ex. brain).

(2) The specification discloses that the cDNA library includes several DNA fragments detected specifically in an important organ/cell (ex. cancer cell).

The USPTO points out that the determination of the presence of Industrial Applicability requires additional facts in this example.

On the other hand, the EPO reveals that the industrial applicability of the cDNA library is acknowledged because such a cDNA library can be used in industry for the isolation and cloning of organ specific cDNAs coding for organ specific proteins.

The JPO also mentions that it is possible to make an inference that the information relating to "a cDNA library originating in an important organ" can be used for research and development of the functions, etc. of the organ, and therefore the industrial applicability is met.

(3) The specification discloses that the cDNA fragment cloned from the cDNA library encodes a protein and the function of the said protein is also expected to a certain extent.

(4) The specification discloses that the cDNA fragment cloned from the cDNA library encodes a protein and the function of the said protein was confirmed by in experiment.

As to given examples, the USPTO shows that the examiner must analyze the specification to determine whether the invention can be made or used in any kind of industry where industry is considered in its broadest sense.

The EPO replies positively in each question but points out that it is a question of plausibility as to whether the function of said protein can be expected or not concerning question (3).

The JPO mentions that the industrial applicability both for "a cDNA library" and for "a cDNA fragment encoding a protein, wherein the function of the said protein was confirmed by an experiment" is met.

## **2.2 Novelty**

Please explain determination whether the claimed invention (Y') has novelty over the prior art (Y) in each below case (1) - (7), while taking into account relationship

between filing date and prior art as mentioned in the following case (a) and (b) respectively;

(a) where a prior art document (Y) was published before the filing of the application (Y')

(b) where another application (Y) was filed prior to the date of filing of the application (Y') and was published after that date.

Y : a prior art or another application

Y' : a claimed invention

Again, the three Offices present the general discussion in front of their answers.

In the USPTO, "lack of novelty" is also known as "anticipation". A single prior art reference anticipates a claimed invention only if it discloses each and every claim element. An unclaimed limitation will not avoid anticipation.

The EPO explains that the content of European patent applications as filed, of which the dates of filing are prior to the date of filing of the application in question and which were published on or after that date, are considered under Article 54(3) EPC as comprised in the state of the art, in so far as a "contracting state" designated in respect of the later application, was also designated in respect of the earlier application as published.

In the JPO, an "invention described in a publication" means an invention which a person skilled in the art can identify on the basis of the matters either described or essentially described, though not literally, in a publication. Furthermore in case (b), where there is a difference between the two, they are deemed identical (substantially identical) if the difference is considered as a very minor difference (addition, deletion, or replacing of well-known or commonly used art, generating no new effects) in embodied means to solve a problem.

(1) Y : a structural gene encoding a functional polypeptide, the whole sequence of which is disclosed

Y' : a partial DNA fragment of Y

Does determination on novelty depend on whether the invention is claimed as "nucleotide" (chemical substance) or "probe" (use) ?

The three Offices present the similar result in general, i.e., such an invention which relates to this partial sequence is regarded as being novel, when an invention relating to a partial sequence has not been disclosed in concrete terms in publicly known literature; and the same determination is made, regardless of whether the claimed invention is a "nucleotide" or a "probe".

In addition, the USPTO shows that the claimed fragment could lack novelty if the fragment were claimed using open ended language such as "comprising" and claims

directed to a method of using Y' might be novel even for open ended claim language such as "a method of using a probe comprising Y' .

The EPO states that it should be noted that the use to which a product is put does not in itself render the product novel (exception first medical use).

(2) Y : a DNA encoding human protein X

Y' : a certain DNA sequence encoding an allelic mutant of human protein X, which has several different codons from specific DNA sequences described in prior art (Y).

The three Offices point out that it would be novel because of having different nucleotides/codons.

The JPO additionally suggests, however, that the claimed invention and the cited invention are deemed substantially identical, when the claimed invention relating to a sequence of an allelic mutant, which has the same properties and functions and has the same origin as the sequence disclosed in the specification of a prior application, is defined in such a comprehensive way as hybridization type claims or addition/deletion/substitution type claims.

(3) Y : a DNA encoding mouse protein X

Y' : a DNA encoding human protein X, the function and the sequence of which are similar to that in prior art (Y)

We can see the same result that novelty is present in both cases a and b.

(4) Y : a viral antigen, the whole amino acid sequence of which is disclosed

Y' : a partial polypeptide fragment (utilized as an epitope which the viral antigen (Y) has on it)

The tendency of result is similar to 2.2(1), i.e., the novelty is present in general.

The EPO and the JPO explain the exceptional cases; in the EPO, novelty might be acknowledged for polypeptide fragments carrying the defined epitope not disclosed in the prior art document.

The JPO shows that if an invention in a later application is defined in a comprehensive claim which includes any polypeptide fragment useful as an epitope and has no concrete confirmation by way of a working example, etc., it is substantially identical to the sequence described in the specification of a prior application.

(5) Y : protein X, but obtained by the process which is not recombinant DNA technology

Y' : recombinant protein claimed as "product-by-process" product, which is the same product as protein X.

Again, the three Offices point out that it would not be novel because it is irrelevant how it is created if it is the same product.

Furthermore, each Office explains its exceptional cases, namely "the recombinant product can be shown to have higher purity or some other attribute conferring patentability not found in the prior art" (the USPTO), "the recombinant protein is novel if the recombinant process inevitably leads to a different product" (the EPO) and "in cases where a prior art document or a prior application merely suggests that a protein exists naturally but it does not disclose that the protein has been purified to the extent that the said protein becomes substantially only one component, a later filed invention relating to said protein specified by amino-acid sequence, which is produced as a recombinant protein by using recombinant DNA technology, has novelty" (the JPO).

(6)Y : a monoclonal antibody which binds to antigen A

Y' : a monoclonal antibody which binds to antigen A'

(the antigen A' itself has novelty, but antigen A may have the same epitope as that of A' on itself because antigen A is closely similar to antigen A'.)

If antigen A' is a modified protein of antigen A, is the above judgement the same ?

The USPTO points out the two facts, that antigen A would be expected to have many of the same epitopes as antigen A' if antigen A is very similar to antigen A'; however, if the claim is drawn to the a monoclonal antibody of a specific hybridoma, there would be novelty because the creation of the monoclonal hybridoma is a stochastic event arising from a large number of different variables.

In the EPO, novelty can only be recognized for a monoclonal antibody binding to antigen A' if the antibody is defined by technical features distinguishing it unambiguously from the monoclonal antibody known from the prior art; and the same conclusion will be reached if antigen A' is a modified protein of antigen A.

The JPO states that if antigen A' is novel, a monoclonal antibody to the novel antigen A' generally has novelty in both cases a and b.

However, novelty could be denied if it can be established that the claimed monoclonal antibody is likely to be "identical" to the monoclonal antibody described in a prior art document or a prior application.

(7)Y : a structural gene encoding protein X, which is disclosed as a generic claim (ex. "hybridize" claim, an "addition-deletion-substitution" claim etc.)

Y' : a specific DNA sequence, which encodes protein X and which is different from the sequences disclosed in (Y)

(7-1)

In case where the effect of the DNA sequence in (Y') is the same as that of the DNA sequences in (Y)

(7-2)

In case where the effect of the DNA sequence in (Y') is better than that of the DNA sequences in (Y)

The criteria of judging novelty are almost similar among the three Offices; a generic disclosure does not deny the novelty of any specific example, falling within the terms of that disclosure.

However, the JPO gives the answer different from that of the other two Offices; in case b of (7-2), Y' and Y are determined not substantially identical when Y' has new effect, even if Y' is obtainable by applying well-known or commonly used art to what is substantially disclosed in the specification of Y, for example, when Y' has a very small number of deletion at the side of 5'- or 3'- terminal of structural gene disclosed concretely in the specification of Y.

### **2.3 Inventive step (Non-obviousness)**

Please explain determination whether the claimed invention (Y') has inventive step over the prior art (Y) in each below case (1) - (7).

(1)

Y : a structural gene encoding a functional polypeptide, the whole sequence of which is disclosed

Y' : a partial DNA fragment of Y

The USPTO only suggests that an assessment of the entire state of the art as well as the information contained in the specification.

The other two Offices answer usually no, since it is merely a normal and common procedure for a person skilled in the art to obtain a partial DNA sequence on the provision that the corresponding whole sequence of the structural gene has been known from the prior art; However, a DNA fragment encoding a protein having some unexpected property vis a vis the known protein may be acknowledged as inventive.

In general, the USPTO agrees with the EPO and the JPO position.

(2)

Y : a DNA encoding human protein X

Y' : a certain DNA sequence encoding an allelic mutant of human protein X, which has several different codons from specific DNA sequences described in prior art (Y).

The tendency of the results is similar to the above mentioned question 2.3(1).

The USPTO only suggests that an assessment of the entire state of the art as well as the information contained in the specification.

On the other hand, the other two Offices answer usually no, because it is a common practice in this field of technology.

However, when the obtained specific DNA has an effect which is either qualitatively different from the that of prior art or qualitatively homogeneous but quantitatively superior, inventive step is present if a person skilled in the art cannot expect this effect on the basis of the state of the art.

(3)

Y : a DNA encoding mouse protein X

Y' : a DNA encoding human protein X, the function and the sequence of which are similar to that in prior art (Y)

The tendency of the results is similar to the above mentioned questions 2.3(1) and (2).

The USPTO only suggests of assessment of the entire state of the art as well as the information contained in the specification.

On the other hand, the other two Offices answer usually no because it is a common practice in this field of technology.

However, the JPO states that when the obtained specific DNA has an effect which is either qualitatively different from the that of prior art or qualitatively homogeneous but quantitatively superior, inventive step is present if a person skilled in the art cannot expect this effect on the basis of the state of the art.

The EPO takes the view that a DNA encoding human protein X may exceptionally be considered to involve an inventive step if there was a prejudice in the art against the cloning of the human DNA encoding protein X and/or the applicant provided clear evidence that the mere employment of conventional techniques of molecular biology and recombinant DNA technology would not have resulted in the isolation of the claimed human DNA.

(4)

Y : a viral antigen, the whole amino acid sequence of which is disclosed

Y' : a partial polypeptide fragment (utilized as an epitope which the viral antigen (Y) has on it)

The three Offices have the same opinion to this question, i.e., it is within the range of ordinary creative ability to obtain any partial polypeptide fragment of the whole viral antigenic protein when the whole amino acid sequence of the viral antigenic protein is publicly known, and the search for the effective sites as the epitope on the viral antigenic protein is a problem which can be easily come up with by a person skilled in the art.

However, if the selection from the known broad class provides a surprising technical property or effect, the partial polypeptide fragment containing an epitope having surprising effects is regarded to be inventive.

(5)

Y : a monoclonal antibody which binds to antigen A

Y' : a monoclonal antibody which binds to antigen A'

(the antigen A' itself has novelty, but antigen A may have the same epitope)

as that of A' on itself because antigen A is closely similar to antigen A'.)

If antigen A' is a modified protein of antigen A, is the above judgement the same ?

This question has reference to prior question 2.2(6).

The three Offices point out that generic monoclonal antibody which binds to antigen A' does not have inventive step.

As to a modified protein, the USPTO and the JPO explain that there is no difference in the above judgement even if antigen A' is a modified protein of antigen A.

(5') If the monoclonal antibody to the antigen A is publicly known, does the invention of the monoclonal antibody to the antigen A specified by technical means which is able to distinguish from the said publicly known monoclonal antibody (ex. "class or subclass of immunoglobulin", "produced by the deposited hybridoma", "cross reactivity") have the inventive step ?

The answers are different, depend on the technical means which specifies the monoclonal antibody.

The three Offices agree that the monoclonal antibody to the antigen A which is specified by "class or subclass of immunoglobulin" would not have normally an inventive step.

The USPTO states that the monoclonal antibody to the antigen A which is specified by "produced by the deposited hybridoma" would normally have an inventive step, even if other similar monoclonal antibodies are publicly known.

The EPO and the JPO reply that deposition of the hybridoma does by itself give rise to an inventive step.

The EPO and JPO state that the monoclonal antibody to the antigen having different "cross reactivity" than the monoclonal antibody already publicly known would normally have an inventive step.

On the other hand, the USPTO only replies that it may be possible to screen for monoclonal antibodies with cross reactivity to other proteins.

(6)

Y : protein X, a partial amino acid sequence of which is known

Y' : a DNA sequence encoding protein X

The USPTO explains that obviousness is a very fact-dependent determination which must be made in every application, based on the facts of that case and the state of the prior art at the time of the filing; no per se rules of obviousness exist.

The EPO gives negative answer, even though no partial amino acid sequence of protein X has been disclosed in the prior art but protein X was described in a highly purified form which would make it possible for a skilled person to sequence protein X.

The JPO states that inventive step generally cannot be recognized in such a case, when there is a high probability to obtain (to clone) a whole DNA sequence which encodes protein X by obtaining the said probe encoding the partial amino acid sequence of Y; however, when it is recognized that the cloning of the entire DNA sequence from the said probe is a difficult task, or when the effect achieved by a cloned specific DNA encoding protein X is either qualitatively different from that of prior art, or qualitatively superior, even if the quality is the same, and this effect cannot be expected by a person skilled in the art on the basis of the state of the art, then, inventive step is present .

(7)

Y : a transformant transformed with a DNA sequence encoding for protein X.

(P1, P2, P3, P4, P5, ... PM as examples of promoters are described, and H1, H2, H3, H4, H5, ... HN as examples of hosts are described. Only the combination of P1 and H1 is used in the working example.)

Y' : a transformed H5 with a DNA sequence encoding for protein X, which is regulated by promoter P5 (The effect of the transformant in (Y') is better than that of the transformant in the working example of (Y).)

Would the answer depend on the number of "M" or "N" ?

The USPTO shows that the assessment of the existence of an inventive step involving the selection of specific listed members of a genus does not turn solely on the number of members of the genus, but must be assessed in light of the remainder of the art.

The EPO and the JPO explain that the claimed invention seems to be a so called selection invention for which an inventive step can be recognized. In addition, the JPO reveals that this judgement does not usually depend on the number of M or N, but if the number of M or N is extremely small so that the number of the alternatives is very small, and if there is incontestable reasoning that a person skilled in the art could have easily arrived at a claimed invention based on a cause or a motivation, inventive step is denied regardless of advantageous effects of a claimed invention.

### **3. Unity of Invention**

Do you think that all claims have unity of invention in each of below cases ?

The USPTO and the EPO present the general direction.

In the USPTO, the unity of invention standard is applied only to those applications filed under the PCT. The presence or absence of a "common technical feature" in the claims is the determining factor for unity of invention. The determination of unity of invention requires an evaluation of the specification, as well as, the claims.

The EPO shows the terminology "special technical feature"; this means those features which each of the claimed inventions considered as a whole makes over the prior art.

(1)

1. polypeptide fragment A of Virus C antigenic protein. (utilized as an epitope of Virus C antigenic protein)
2. polypeptide fragment B of Virus C antigenic protein. (utilized as another epitope of Virus C antigenic protein)

\*The amino acid sequence of fragment A is quite different from that of fragment B.

Both the EPO and the JPO explain that the requirement of unity of invention would not be satisfied when a polypeptide fragment other than the claimed fragment which is useful as an epitope on the said viral antigenic protein is publicly known; on the other hand, unity of invention could be present, if Virus C was novel and inventive (the EPO), or if multiple groups of epitopes on a viral antigenic protein encoded by a single gene were not known before the filing (the JPO).

(2) A group of DNA sequences all of which have the same source (ex. all are cloned from a human brain) and each function of which is different/unknown.

The EPO, the USPTO and the JPO state the requirement for the unity of invention would not be satisfied because the source of a DNA sequence does not constitute a technical feature of the sequence itself (the EPO), such sequences do not have the same technical problem to be solved and the substantial part of the matters being to be stated in each claim is not the same (the JPO).

(3) A group of monoclonal antibodies prepared by the same antigen A.

\*Does the judgement depend on whether antigen A itself is novel or known ?

The EPO answers that a claim directed to a group of monoclonal antibodies having different properties would lack unity if antigen A were known; unity would be recognized if the claimed monoclonal antibodies share a novel, non-obvious feature, or antigen A is novel and inventive.

The JPO answers that the requirement of the unity is satisfied whether antigen A is novel or known, as long as no monoclonal antibodies to antigen A are known; when at least one of the monoclonal antibodies to antigen A is publicly known as of the filing, the requirement for the unity of invention would not be satisfied.

## **4. Amendment**

### **4.1 Amendment of DNA/amino acid sequence**

(1) In what case the correction of DNA/amino acid sequence is permitted, when DNA/amino acid sequence has errors in the specification ?

Is the amendment more likely to be permitted if transformant/vector containing the gene was deposited ?

We can see the differences between the USPTO and the other two Offices.

The USPTO is quite flexible and no general rule exists; i.e., the answer depends on facts in each case and on significance of the modification to both the claimed subject matter and the described subject matter. And also, for example, addition of a DNA sequence during prosecution is not new matter if the DNA had been deposited earlier.

On the other hand, the EPO and the JPO state that it is likely that the case in question is judged as a "new matter", since it can be allowed to amend only what is directly and unambiguously derivable by a person skilled in the art from the matters described in the specification and drawings initially attached.

(2) Where the correction of the DNA/amino acid sequence may be judged as addition of a new matter, is it allowed to describe (or amend) the claimed DNA/amino acid as "product-by-process" form instead of correction of DNA/amino acid sequence ?  
ex. A DNA isolate encoding protein X as obtained by the process of claim 1.  
\*In this case, claim 1 is either specific process or generic process.

The three Offices agree in general, i.e., it is allowed if such a description is recognized as the matter which is directly and unambiguously derivable by a person skilled in the art from the matters described in the specification and drawings initially attached.

#### **4.2 Addition or Conversion of deposit number**

(1) Is it allowed that the amendment adding an accession number of the microorganism, which is not explicitly stated in the specification as filed ?  
If it is allowed, what is the condition ?

Does your answer depend upon whether the application is published before the amendment ?

In the USPTO, the only requirement is that the accession number merely designates what was already disclosed in the application as filed (i.e., no new matter is added), and this does not depend on whether the application is published before the amendment.

The EPO explains that the information concerning the accession number of a culture which has been deposited with a recognized depository institution not later than the filing of the application may not be submitted after the expiry of 16 months after the date of filing; it must be filed up to the date of submitting the request for early publication if the applicant desires.

The JPO shows the practice in accordance with the Examination Guidelines published in June 1993 (applicable to applications filed before 1994.1.1); an amendment of the accession number of a microorganism does not change the gist of the patent specification, where microbiological properties of the microorganism are described to the extent that the microorganism can be specified in the patent specification as filed, and the deposit of the microorganism can be specified based on the name of the depository institution, etc.

(2) Is it allowed that the amendment converting an accession number of a microorganism stated in the specification as filed to a new number, when the applicant re-deposits the microorganism after the application was filed ?

The USPTO replies the same as above described 4.2(1).

The EPO shows the limited and rare case, i.e., (a) the microorganism is no longer viable or (b) for any other reason the depository institution is unable to supply samples and the microorganism has not been transferred to another depository institution recognized by the EPO, from which it continues to be available.

The JPO shows the practice in accordance with the Examination Guidelines published in June 1993 (applicable to applications filed before 1994.1.1); as long as it is clear that identity of the microorganism is not lost, an amendment converting an accession number of a microorganism, with the statement such an amendment is based on only the re-deposition, does not exchange the gist of the patent specification.

## **5. Patentable subject matters**

If there have been any changes on the scope of patentable subject matters (especially inventions of plants themselves and animals themselves), as a result of new interpretations of the law after the issue of the Report in the Field of Biotechnology Related Mainly to Microbiological Inventions" of Project 12.3 (1990.1), of "Consolidated Comparative Study of Patent Practices please report what matters have changed.

The USPTO and the EPO report their new issues, while the JPO states that there have been no changes in these matters.

The USPTO explains some examples of weakening the applicability of Durden case, namely about patents on biotechnological processes of new Section 103(b) and the Federal Circuit's recent case. According to the highest court of US, Congress intended patentable subject matter to include "anything under the sun that is made by man", referring Diamond v. Chakrabarty case.

The EPO answers that the question whether a claim which relates to plants or animals but wherein specific plant or animal varieties are not individually claimed contravene the prohibition on patenting in Article 53(b) EPC if it embraces plant or animal varieties was then referred to the Enlarged Board of Appeal in the EPO, however, it did not give an answer on the question. Therefore, at present the question of the conditions of patentability of claims directed to plants and animals in general remains to be further clarified.