Comparative Study on Hypothetical/Real Cases: Requirements for Disclosure and Claims

1. Introduction

In order for applicants to prepare high quality patent applications, which lead to enhance the examination quality, the Trilateral Offices acknowledged the significance of a comparative study on the requirements for disclosure and claims, and a comparative study on the inventive step.

The results of comparative study will enable applicants to prospect properly the results of the examination and will support them to obtain, worldwide, patents without having a ground of invalidation. The quality improvement of patent applications will contribute to a more timely and proper examination and will lead to the decreasing of the backlog in the end. Therefore, the Offices will consider the dissemination of the results to applicants and attorneys.

In this study, the Offices deal with "Comparative Study on Hypothetical/Real Cases" and "Comparative Study on Laws, the Regulations, the Guidelines etc." as to the requirements for disclosure and claims. This report describes "Comparative Study on Hypothetical/Real Cases." As to the result of "Comparative Study on Laws, the Regulations, the Guidelines etc.", see below.

[Comparative Study on Laws, the Regulations, the Guidelines etc.]

The Trilateral Offices conducted a comparative study on the requirements for disclosure and claims in 1990s named Project 12.6 in view of the discussion on the harmonization of patent practice at that time. The purpose of the study was to identify similarities and differences of each Office's law, regulations, guidelines and practice on several items in detail. However, as many years have passed since then, the controlling laws, the regulations, the guidelines and the practices have been modified and many court cases have been brought.

Therefore, the Trilateral Offices revised the 1990s report as a part of the Comparative Study on Examination Practices. The revised comparative study report is provided below.

The Revised Version of the Comparative Study Report on Trilateral Project 12.6

Requirements for Disclosure and Claims

2. Comparative Study on Hypothetical/Real Cases

The Trilateral Offices presented 1-3 hypothetical cases each to illustrate the requirements for disclosure and claims determination. Then the Trilateral Offices presented each Office's view on determination of the requirements for disclosure and claims based on its own laws, regulations, guidelines, practices etc.

2-1: Questions Common to All Cases

Question: Does the application meet the requirements for disclosure and claims?

"The requirements for disclosure and claims" mean the enablement requirement, the support requirement, the written description requirement, and the clear and concise requirement. (EPO: Art. 83, Art. 84 EPC, JPO: Art.36-4-1, Art. 36-6-1, Art. 36-6-2 Japanese Patent Act, USPTO: 35 U.S.C. 112, 1st paragraph, 2nd paragraph)

2-2: Cases and Results

Case 1

Outline of Case (See Appendix 1 in detail.)

[Claims]

[Claim 1] A method of manufacturing a polarizing film by uniaxially stretching a polyvinylalcohol-based raw material film, wherein the polyvinylalcohol-based raw material film has a thickness in the range of 30 to 100 μ m and the relationship between the complete dissolution temperature (X) in hot water and the equilibrium swelling degree (Y) thereof is defined by the following expressions:

$$Y > -0.0667X + 6.73$$
 (I)

$$X \ge 65$$
 (II)

and the polyvinylalcohol-based raw material film is uniaxially stretched to 1.2 to 2 times the original size thereof in a dyeing treatment process and further to 2 to 6 times the original size thereof in a boron-compound treatment process.

[Description]

It is desired to develop a method for manufacturing an excellent polarizing film having a high polarization performance and durability performance by using a film not susceptible to film breakage even if excessive stretching force is applied, namely, a film that can stand being highly stretched.([0007])

Accordingly, the present inventors have conducted intensive studies in order to solve the above-mentioned problems, and, as a result, have found that the above-mentioned object can be achieved by the method below. Thus, the present invention has been accomplished. That is, in a method of manufacturing a polarizing film by uniaxially stretching

a polyvinylalcohol-based raw material film, the polyvinylalcohol-based raw material film has the relationship between the complete dissolution temperature (X) in hot water and the equilibrium swelling degree (Y) thereof is defined by the expressions above. ([0008])

Followings are described as examples and comparative examples. It is described that examples have excellent moisture and heat resistances and was recognized as being a highly durable polarizing film. ([0021]-[0027])

	Example 1	Example 2	Com. Example 1	Com. Example 2
Complete dissolution temperature (X) (°C)	71.6	72.0	74.5	75.3
Equilibrium swelling degree (Y)	2.4	2.2	1.6	1.6
Range of (Y) <calculated value=""></calculated>	Y > 1.95	Y > 1.93	3 Y > 1.76	Y > 1.71
Temperature of discoloration in water (°C)	63	62	52	54

[Conditions]

[Condition 1]

An application with the [Claims] and [Description] in the Appendix 1 is filed. An amendment is not made, and no [Experimental Evidence] is submitted after the filing. Does the application meet the requirements for disclosure and claims? (In Case 1, [Experimental Evidence] means 8 Experiments and 2 Comparative Experiments other than 2 examples and 2 comparative examples described in [Description]. See "Table 1" and "Fig. 2" in Appendix 1.)

[Condition 2]

An application with the [Claims] and [Description] in the Appendix 1 is filed. Afterwards, [Experimental Evidence] is submitted (for example, in response to the office action). Does the application meet the requirements for disclosure and claims?

[Condition 3]

An application with the [Claims] and [Description] (on the supposition that an application contains the contents of "experimental evidence") in the Appendix 1 is filed. Does the application meet the requirements for disclosure and claims?

[Later experimental evidence]

Is it acceptable to submit the evidence to satisfy the requirements for disclosure and claims after the filing?

Summary of Result

The EPO and the USPTO answer that the requirements for disclosure and claims are met in any condition among the above conditions 1-3. On the other hand, the JPO answers that the application with the [Claims] and [Description] in Appendix 1 does not satisfy the requirements for disclosure and claims.

As for submission of the experimental evidence after the filing, the EPO and the JPO answer that it is not acceptable to submit the experimental evidence after the filing in determining whether the requirements for disclosure and claims are met or not. On the other hand, the USPTO answers it is acceptable.

Answers and Comments by each Office [Condition 1] [EPO]

The EPO's answer is "Yes."

Enough structural information present; two parameters well explained and measurable without exceptional effort; two examples satisfying the parameters, comparative tests present. No further evidence necessary.

"I. The patent claims must clearly define subject-matter for which protection is sought (Article 84 EPC). This requirement may be fulfilled in a claim to a product when the characteristics of the product are specified by parameters related to the physical structure of the product, provided that those parameters can be clearly and reliably determined by objective procedures which are usual in the art.

II. In such a product claim, it suffices to state the physical properties of the product in terms of parameters, since it is not mandatory to give instructions in the claim itself as to how the product is to be obtained. The description must fulfill Article 83 EPC and thus enable the person skilled in the art to obtain the claimed product therein described." (T 94/82, Headnote, OJ /1984, 75).

[JPO]

The JPO's answer is "It is not sufficient."

In the above invention, in order for the statement of the claims to properly comply with the support requirement, it is appropriate to interpret that it is required to describe the technical meaning of the relationship between the scope designated by the above mathematical formulas; and the resultant effect (performance) in "a Detailed Description of the Invention" to such an extent that can convince a person skilled in the art at the time of

filing even if embodiments were not disclosed. Alternatively, it is also appropriate to interpret that, by considering the common general knowledge at the time of filing, insofar as the above technical meaning is within the scope designated by the corresponding mathematical formulas, it is required to describe embodiments via the disclosure to such an extent that convinces a person skilled in the art that the desired effect (performance) can be secured.

However, description merely describes a couple of examples and comparative examples, and there is insufficient evidence to convince a person skilled in the art that the concerned invention could be carried out at the time of filing even when concrete examples were not yet disclosed. (2005 (Gyo-Ke) 10042 (See Appendix 2))

[USPTO]

The USPTO's answer is "the application appears to comply with the enablement, description, and definiteness requirements."

Applicant is not required to provide examples or explain why or how an invention works provided that one of ordinary skill in the art would not have reason to question whether the invention can be made or used.

As for two working examples, see, e.g., In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970) (The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation.).

[Condition 2]

[EPO]

The EPO's answer is "Yes."

[JPO]

The JPO's answer is "it is not sufficient."

See [Later experimental evidence] below.

[USPTO]

The USPTO's answer is "Yes."

Later experimental evidence may be relied upon to show that the invention as claimed complied with the enablement requirement at the time the invention was made.

[Condition 3]

[EPO]

The EPO's answer is "Yes."

[JPO]

It is said that the requirements for disclosure and claims are met, if an examiner judges that the detailed description of the invention is described in such a manner that a person skilled in the art can carry out the claimed invention on the basis of matters described in the description which contains 2 examples and 2 comparative examples considered in condition 1 and contents of "experimental evidence", taking into consideration the common general knowledge as of the filing.

[USPTO]

The USPTO's answer is "Yes."

[Later experimental evidence]

In the EPO practice, additional technical information can be filed, although not included into the application documents, only for the purpose of supporting the presence of an inventive step, NOT sufficiency of disclosure.

[JPO]

In Case 1, even when considering the common general knowledge at the time of filing, it is conceived to be impractical to expand or generalize the matters described in "a Detailed Description of the Invention" up to the scope of the claimed invention without disclosing embodiments in "a Detailed Description of the Invention" by an extent enabling a person skilled in the art to conceive that problems of the corresponding invention can be solved.

Nevertheless, the applicant dares to supplement the matters described in "a Detailed Description of the Invention" by submitting the experimental data after filing of the application, thereby resulting in the expansion and generalization of the matters described in "a Detailed Description of the Invention" up to the scope of the claimed invention so as to comply with the support requirement. This procedure taken by the applicant is contradictory to the intent of the patent system beyond the permissible range. (2005 (Gyo-Ke) 10042 (See Appendix 2))

[USPTO]

The USPTO does not require an applicant to include working embodiments in the

application as originally filed. While later experimental evidence cannot be added to the description to overcome an enablement rejection, an applicant is permitted to rely upon later experimental evidence to rebut such a rejection and to show that the invention as claimed complied with the enablement requirement at the time the invention was made.

As for later experimental evidence to show enablement, see, e.g., In re Brandstadter, 484 F.2d 1395, 1406-07, 179 USPQ 286, 294 (CCPA 1973)(Applicant is entitled to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would be able to make and use the claimed invention using the application as a guide.). Applicant may submit factual affidavits under 37 CFR 1.132 or cite references to show what one skilled in the art knew at the time of filing the application; applicant may also provide a declaration after the filing date with experimental evidence which demonstrates that the claimed invention works, provided the experiments used the guidance in the specification as filed and what was well known to one of skill in the art at the time the application was filed.

Other comments

[EPO]

The claim complies with the requirements of sufficiency of disclosure (Art. 83 EPC), since at least one way of carrying out the invention is provided, the parameters are measurable and well explained and comparative tests are present. Whether the technical problem is solved over the whole range will be an issue for the inventive step discussion.

[JPO]

In the presented case, an infinite number of formulae other than the mathematical formula specified in the claim can be set to divide the working examples from the comparative examples because there are only two of each in the description. And it is not clear to the person skilled in the art whether the invention has a desired effect within the whole range specified in the claims distinguished by the straight lines expressed by the formula in light of the common technical knowledge at the time of filing.

Therefore, the claimed invention which indicates the scope where the invention claimed to have a desired effect is not adequately supported by the four embodiments.

[USPTO]

The claim complies with the written description requirement of 35 U.S.C. 112, first paragraph as the applicant has described the invention in a manner sufficient for one skilled in the art to recognize that applicant invented (i.e., was in possession of) the subject matter that is claimed. However, as noted in the original answer, if one skilled in the art would

have reason to question whether the claimed invention can be made or used within its full scope, then the claim would not comply with the enablement requirement.

Case 2

Outline of Case (See Appendix 3 in detail.)

[Claims]

[Claim 1] A composite film comprising linear low-density polyethylene comprising;

a layer A comprising linear low-density polyethylene comprising $0.3 \sim 2.0$ wt% of inert particles each having $3 \sim 15 \mu m$ of average particle size, wherein the density of the linear low-density polyethylene is defined to be $0.88 \sim 0.91$ g per cubic centimeter, wherein said linear low-density polyethylene has $1 \sim 3$ of the ratio between the weight average molecular weight and the number average molecular weight; and

a layer B comprising linear low-density polyethylene comprising $0.3 \sim 1.5$ wt% of inert particles each having $2 \sim 7 \mu m$ of average particle size, wherein the density of the linear low-density polyethylene is defined to be more than 0.905g per cubic centimeter, wherein said density is higher than that of said linear low-density polyethylene available for composing the above layer A.

[Description]

The object of the present invention is providing a novel composite film comprising linear low-density polyethylene incorporating excellent adhesion under low temperature, with satisfactory anti-blocking characteristics, and stable rigidity. ([0003])

In order to produce the inventive linear low-density polyethylene available for composing layer A, it is allowable to solely apply the above-cited ingredients having specific physical characteristics within the above-defined range. Alternatively, it is also allowable to apply more than two kinds of the above ingredients in mixture such that the weighted average value can be held within the above-defined range. It is desired that the above-specified ingredients shall solely be used for composing the linear low-density polyethylene in particular. To embody the present invention, it is essential that layer A shall contain 0.3wt% ~ 2.0wt% of inert particles each having $3 \sim 15$ µm of average particle size. If the average particle size were less than 3µm, the sliding characteristics and anti-blocking characteristics would respectively be degraded, and thus, it is not desirable. Desirably, the average particle size shall range from 5µm up to 12µm. ([0010])

To embody the present invention, it is essential that layer B shall contain 0.3wt% up to 1.5wt% of inert particles each having $2\mu m \sim 7\mu m$ of average particle size. If the average particle size were less than $2\mu m$, the sliding characteristics and anti-blocking characteristics would respectively be lowered, and thus, this is not desirable. Conversely, if the average particle size exceeds $7\mu m$, it will degrade the film appearance, and thus, this is also undesirable. It is desired that the average particle size shall be in a range from $3\mu m$ up to

6µm. ([0016])

[Conditions]

[Condition 1]

An application with the [Claims] and [Description] in the Appendix 3 is filed.

The description does not include the specific conditions that enable the inert particles to satisfy the range of the average diameter of the claimed invention. Is the description of the average size of the inert particles sufficient for the invention to be carried out?

If not, is there anything else other than the average size of the inert particles in the description that is necessary to satisfy the enablement requirement?

[Condition 2]

An application with the [Claims] and [Description] (on the supposition that the description includes a method of measuring) in the Appendix 3 is filed.

Does the application meet the requirements for disclosure and claims?

[Condition 3]

An application with the [Claims] and [Description] (on the supposition that the description includes a manufacturer and a product name of the inert particles) in the Appendix 3 is filed.

Does the application meet the requirements for disclosure and claims?

Summary of Result

As for the condition 1 and 2, the EPO answers "Probably yes" or "Yes". The JPO answers that the requirements for disclosure and claims are not met. The USPTO answers that it depends on what is already known in the art.

As for the condition 3, the EPO and the USPTO answer that the requirements for disclosure and claims are met, while the JPO answers that the requirements for disclosure and claims are not met.

Answers and Comments by each Office

[Condition 1]

[EPO]

The EPO's answer is "Probably yes."

Art. 83, 84 EPC. Rather than the way of measuring the particles, the problem could be whether the skilled person is sufficiently aware of how to incorporate the particles into the

polymers, although from the description, stating that the particles should be heat-resistant ("irresolvable"? p. 11 of the Appendix 3), it appears that they have simply to be mixed into the molten polymer when ready for molding. This appears to be also the teaching of the examples. These remarks are valid if the interpretation of claim 1 and the description is correct.

Art 84 EPC states that the European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art. The person skilled in the art is presumed to be an ordinary practitioner in a field of technology aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the "state of the art", in particular the documents cited in the search report, and to have had at his disposal the normal means and capacity for routine work and experimentation (Guidelines C-IV, 11.3). Whether the disclosure will allow the skilled man to carry out the claimed invention can only be decided on a case by case basis (long-standing practice in patent prosecution, supported by no less well-established case law).

[JPO]

The JPO's answer is "No."

The scope of the invention is not definite, and the description doesn't meet the enablement requirement.

The numerical range of the average particle diameter is significantly variable depending on the definitions and meanings of the average particle diameter, and also depending on the method of measuring the average particle diameter. Any of the above definitions, the meanings, and the measurement methods have actually been used. In addition, since it is not recognizable that a person skilled in the art can commonly and normally conceive adoptable the definition, the meaning, and the measurement method of the average particle diameter of available inert particles (if not being described in the Description), it is quite necessary to properly define the above requirements in the Description.

Insofar as the invention fails to specify the definition of the average particle diameter, the names of the manufacturers and the product names of the applicable inert particles, this in turn causes a person skilled in the art to be uncertain of the appropriate spherical inert particles each having a definite average particle diameter. Due to this reason, it is quite apparent that the invention cannot practically be carried out by a person skilled in the art. (2004 (Gyo-Ke) 290 (See Appendix 4))

[USPTO]

The USPTO's answer is "Maybe."

With regard to the enablement requirement, while the description does not include the specific conditions that enable the inert particles to satisfy the claimed range, it is unclear whether one of ordinary skill in the art would, nonetheless, be able to make and use the claimed invention based on what is already known in the art. Thus the description of the average size of the inert particles may or may not be sufficient to make and use the claimed invention.

As for size of particles and method of measuring, see, e.g., United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991).

[Condition 2]

[EPO]

The EPO's answer is "Yes."

No disclosure problem as the skilled person would probably know how to measure the particles.

[JPO]

The JPO's answer is "No."

The scope of the invention is not definite, and the description doesn't meet the enablement requirement.

With regard to the method of determining the average particle diameter of the inert particles, there are many kinds of methods including the number average particle diameter, the length average particle diameter, and the volume average particle diameter and formulas for calculating these factors differ from each other. When measuring the average particle diameter related to a simplified distribution model, depending on any of the applied basis including the length, planar dimension, and the volume, it is understood that there is a substantial difference among the individual methods by a maximum of approximately 10%. Therefore, the numerical range of the average particle diameter is significantly variable depending on the definitions and meanings of the average particle diameter.

Insofar as the invention fails to specify the definition of the average particle diameter, the names of the manufacturers and the product names of the applicable inert particles, this

in turn causes a person skilled in the art to be uncertain of the appropriate spherical inert particles each having a definite average particle diameter. Due to this reason, it is quite apparent that the invention cannot practically be carried out by a person skilled in the art. (2004 (Gyo-Ke) 290 (See Appendix 4))

[USPTO]

The USPTO's answer is "Maybe."

The condition states the description includes a "method of measuring." Assuming this refers to a method of measuring the size of the inert particles, the issue is whether one skilled in the art could make and use the claimed invention. If one skilled in the art could measure the particles, but could not make or otherwise obtain them, the disclosure would fail to meet the enablement requirement.

[Condition 3]

[EPO]

The EPO's answer is "Yes."

No necessity of providing name or manufacturer of the particles.

[JPO]

The JPO's answer is "No."

Even on condition 3, the scope of the invention is not definite, and the description doesn't meet the enablement requirement.

The Description is devoid of any description to explain that if only the nominal range of spherical inert particles announced by the corresponding manufacturers correctly meet the numerical range of the average particle diameter described in Claims, any of such inert particles can be used as the particles described in Claims. Actually, there is no evidence enough to believe that nominal range of the above spherical inert particles announced by corresponding manufacturers correctly meet the numerical range of the average particle diameter described in the Claims. There are a variety of the definitions and the methods for measuring the average particle diameter, and many kinds of the measurement methods have actually been applied, and yet, the resultant numerical range is significantly variable. Hence, it is not found that a person skilled in the art believes that the numerical range of the inert particles used for carrying out the invention is coincident with the nominal range announced by corresponding manufacturers.

[USPTO]

The USPTO's answer is "Yes."

If the description includes a manufacturer and product name for the inert particles, then one skilled in the art would be able to obtain the necessary materials to make and use the claimed invention.

As for manufacturer and product name known, see, e.g., In re Argoudelis, 434 F.2d 1390, 168 USPQ 99 (CCPA 1970)(availability of the biological product via a public depository provided an acceptable means of meeting the written description and the enablement requirements of 35 U.S.C. 112, first paragraph); Ex parte Thomson, 24 USPQ2d 1618 (Bd. Pat. App. & Inter. 1992) (Seeds were commercially available more than 1 year prior to applicant's filing date. One of ordinary skill in the art could grow the claimed cotton cultivar from the commercially available seeds. Thus, the publications describing the cotton cultivar had enabled disclosures.).

Other comments

[EPO]

The skilled person would certainly know one or more methods to measure the particle size. If the measuring method is not clearly indicated in the description, the applicant could run the risk that a prior art item accidentally falls within the indicated ranges, but this is no matter of sufficiency of disclosure.

[JPO]

In this case, it is the common general knowledge in this field that there are several types in terms of definition and method of measuring, etc. of average size of the particles, and that the person skilled in the art does not have the same view about which type is usually used.

[USPTO]

The description of the average size of the inert particles may or may not be sufficient to make and use the claimed invention. The description does indicate that particle size is a critical aspect of the claimed invention in that it is essential for each of layers A and B to contain the specified weight percentage of inert particles having the specified average particle size. However, if the art-recognized methods of measuring average size result in either very similar or very different results, the specific method of measuring may be either unimportant (if results would be similar) or readily apparent (if the results would be appreciably different).

Case 3

[Claims]

[Claim 1] An isolated protein comprising Protein A,

wherein said Protein A includes the amino acid sequence of SEQ ID NO: 1 in the N-terminal portion of the protein, and has the same ability to bind to and activate Protein X as Protein A from human urine, and

wherein said Protein A is purified by subjecting a crude protein recovered from a dialyzed concentrate of human urine to affinity chromatography on a column of immobilized Protein X, and elutes from a reversed-phase HPLC column as a single peak in a fraction corresponding to about 31% acetonitrile and shows a molecular weight of about 22 kDa when measured by SDS-PAGE under reducing conditions.

[Claim 2] An isolated DNA comprising a contiguous DNA that encodes Protein A,

wherein said Protein A includes the amino acid sequence of SEQ ID NO: 1 in the N-terminal portion of the protein, and has the same ability to bind to and activate Protein X as Protein A from human urine, and

wherein said Protein A is purified by subjecting a crude protein recovered from a dialyzed concentrate of human urine to affinity chromatography on a column of immobilized Protein X, and elutes from a reversed-phase HPLC column as a single peak in a fraction corresponding to about 31% acetonitrile and shows a molecular weight of about 22 kDa when measured by SDS-PAGE under reducing conditions.

[Description]

The description discloses a working example in which Protein A was isolated from human urine. Protein A is a 22 kDa protein that binds to and activates Protein X. Example 1 describes a process for isolating Protein A from human urine. The process includes dialyzing human urine to form a crude protein concentrate, loading the protein concentrate onto an affinity column of immobilized Protein X, and eluting Protein A from the column as a single peak in a fraction corresponding to about 31% acetonitrile using reversed-phase high pressure liquid chromatography (HPLC), wherein the purity of Protein A is confirmed by SDS-PAGE under reducing conditions. The example provides data showing that Protein A so isolated binds to and activates Protein X. The description also discloses a 10 amino acid sequence from the N-terminus of Protein A (identified as SEQ ID NO: 1).

Prophetic examples are also provided for making a library of cDNAs encoding Protein A using random primers in combination with primers based on nucleic acid sequences

predicted from the disclosed 10 amino acid sequence of the N-terminus of Protein A.

Summary of Result

The Trilateral Offices share the point that the requirements for disclosure and claims are met with respect to claim 1, and not met with respect to claim 2.

Answers and Comments by each Office [Claim 1]

[EPO]

The EPO's answer is "Yes."

The claim is clear (Art. 84 EPC); disclosure also sufficient (Art. 83 EPC) due to the process steps for the isolation, the indication of the chromatographic data and the SDS PAGE molecular weight (example).

"I. The patent claims must clearly define subject-matter for which protection is sought (Article 84 EPC). This requirement may be fulfilled in a claim to a product when the characteristics of the product are specified by parameters related to the physical structure of the product, provided that those parameters can be clearly and reliably determined by objective procedures which are usual in the art.

II. In such a product claim, it suffices to state the physical properties of the product in terms of parameters, since it is not mandatory to give instructions in the claim itself as to how the product is to be obtained. The description must fulfil Article 83 EPC and thus enable the person skilled in the art to obtain the claimed product therein described." (T 94/82, Headnote, OJ /1984, 75).

[JPO]

The JPO's answer is "Yes."

The JPO considers the requirement for disclosure and claims on the presumption that the invention concerning claim 1 is "An isolated Protein A, wherein said Protein A includes the amino acid sequence of SEQ ID NO: 1 in the N-terminal portion of the protein, and has the same ability to bind to and activate Protein X as Protein A from human urine, and wherein said Protein A is purified by subjecting a crude protein recovered from a dialyzed concentrate of human urine to affinity chromatography on a column of immobilized Protein X, and elutes from a reversed-phase HPLC column as a single peak in a fraction corresponding to about 31% acetonitrile and shows a molecular weight of about 22 kDa when measured by SDS-PAGE under reducing conditions."

The description discloses the method for isolating Protein A and the working example.

Therefore, if claim 1 is described as "An isolated Protein A,...", the description satisfies the support requirement (Requirement of Article 36(6)(i)) and the enablement requirement (Requirement of Article 36(4)(i)). (See "Other Comments" below.)

[USPTO]

The USPTO's answer is "Yes."

35 U.S.C. 112, 1st para. The specification discloses a partial structure of Protein A, other relevant identifying characteristics, how to isolate Protein A from human urine, and a working example. (See "Other Comments" below.)

[Claim 2]

[EPO]

The EPO's answer is "No."

Lack of definition in claim 2 even worse than in claim 1, because only a small portion of the claimed DNA can be drawn from the partial structure of the protein A, and there is no link between the function of the protein A (binding prot. X) and its DNA. The skilled person would have no unambiguous information on how the claimed compound looks like nor how to make it (Art. 83, 84 EPC).

It should be noted that, although an objection of lack of support is an objection under Art. 84 EPC, it can often also be considered as an objection of insufficient disclosure of the invention under Art. 83 EPC, the objection being that the disclosure is insufficient to enable the skilled person to carry out the "invention" over the whole breadth of the claim. (Guidelines, C-III, 6.4)

[JPO]

The JPO's answer is "No."

A person skilled in the art can recognize only 5% of the sequence of the claimed DNA. The description fails to disclose the working example.

Consequently, a large amount of trials and errors or complicated experimentation is needed to isolate the claimed DNA beyond the reasonable extent that can be expected from a person skilled in the art.

Therefore, the description fails to satisfy the Requirement of Article 36(6)(i) and the Requirement of Article 36(4)(i). (See "Other Comments" below.)

[USPTO]

The USPTO's answer is "No."

35 U.S.C. 112, 1st para. The specification fails to disclose the complete structure of any DNA encoding protein A or the complete structure of protein A; or any art-recognized correlation between structure and the disclosed function of the claimed DNAs; or sufficient identifying characteristics to distinguish the claimed DNAs from other DNAs of similar size. (See "Other Comments" below.)

Other Comments

[EPO]

(Claim 1) Biological material may be isolated from its natural environment and further characterised by parameters, provided that those parameters can be clearly and reliably determined either by indications in the description or by objective procedures which are usual in the art (Use of parameters: EPO Board of Appeal decision T 94/82, OJ /1984, 75).

[JPO]

(Claim 1) The JPO considers the requirements for disclosure and claims on the presumption that the invention concerning claim 1 is "An isolated Protein A,...".

The description discloses Protein A isolated from human urine, its molecular weight, its ability to bind and activate Protein X, and the 10 amino acid N-terminal sequence of SEQ ID NO: 1. The description also discloses the method for isolating Protein A from human urine and the working example in which Protein A is successfully isolated using the disclosed method. Therefore, the description is sufficient for enabling a person skilled in the art to isolate the claimed protein.

Accordingly, the description satisfies the support requirement (Requirement of Article 36(6)(i)) and the enablement requirement (Requirement of Article 36(4)(i)).

(Claim 2) The description discloses Protein A isolated from human urine, its molecular weight, its ability to bind and activate Protein X, and the 10 amino acid N-terminal sequence of SEQ ID NO: 1.

However, it is only 10 amino acid N-terminal sequence that has determined among the sequence of Protein A. While a person skilled in the art can recognize about 5% of the sequence of the claimed DNA, judging from the molecular weight of Protein A, the sequence of the remaining 95% of the claimed DNA is still unknown. Although the description discloses a prophetic example showing how to isolate the claimed DNA, the description fails to disclose the working example in which claimed DNA is isolated.

Consequently, a large amount of trials and errors or complicated experimentation is needed to isolate the claimed DNA beyond the reasonable extent that can be expected from

a person skilled in the art.

Therefore, the description fails to satisfy the support requirement (Requirement of Article 36(6)(i)) and the enablement requirement (Requirement of Article 36(4)(i)).

[USPTO]

(Claim 1) Claim 1 encompasses proteins having an N-terminal amino acid sequence of SEQ ID NO: 1, and the same ability to bind to and activate Protein X as Protein A from human urine. The claim is generic because it recites the "open" transitional term "comprising." The specification fails to disclose the complete structure of Protein A. The specification also fails to disclose any art-recognized correlation between the structure of the claimed protein and its function of binding and activating Protein X. However, the specification discloses a partial structure of Protein A (i.e., the 10 amino acid N-terminal sequence of SEQ ID NO: 1), and other relevant identifying characteristics of the protein (e.g., its ability to bind and activate Protein X, its approximate molecular weight, and the concentration of acetonitrile at which Protein A will elute from a reverse phase HPLC column). The specification also discloses a method for isolating Protein A from human urine, and a working example in which Protein A is successfully isolated using the disclosed method. Thus, those of ordinary skill in the art of isolating proteins would recognize the inventor to be in possession of the claimed protein at the time of filing based on these identifying characteristics and the disclosed isolation method.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 1.

(Claim 2) Claim 2 encompasses DNAs encoding Protein A that have an N-terminal amino acid sequence of SEQ ID NO: 1, and the same ability to bind to and activate Protein X as Protein A from human urine. The claim is generic because it recites the "open" transitional term "comprising." The specification fails to disclose the complete structure of any DNA encoding Protein A, or the complete structure of Protein A, from which the structures of the claimed DNAs might be predicted based on knowledge in the art of the genetic code. The specification also fails to disclose any art-recognized correlation between structure and the disclosed function of the claimed DNAs (i.e., encoding Protein A) and/or the disclosed function of Protein A (i.e., binding and activating Protein X). The specification does not disclose the isolation or cloning of any DNA that encodes Protein A and/or refer to any deposited DNA capable of coding for Protein A. Although the specification discloses relevant identifying characteristics of Protein A (e.g., its ability to bind and activate Protein X,

its approximate molecular weight, and the concentration of acetonitrile at which Protein A will elute from a reverse phase HPLC column), only Protein A's molecular weight provides any information about the claimed DNAs (i.e., a rough approximation of the size of a cDNA encoding Protein A¹). However, the size of a DNA alone will not distinguish it from other DNAs. Thus, the specification fails to disclose sufficient relevant identifying characteristics of the claimed DNAs.

The specification discloses 10 amino acids of Protein A's approximately 200 total amino acids, and a prophetic example for making a library of DNAs encoding Protein A using random primers and primers based on this amino acid sequence. Using the genetic code, those of ordinary skill in the art could predict all of the nucleic acid sequences able to encode the disclosed 10 amino acids of SEQ ID NO: 1. Thus, those of ordinary skill in the art would recognize the inventor to be in possession of 5% of the structure of the claimed DNAs. However, the specification fails to disclose any information about the structure of the remaining 95% of the claimed DNAs. Although the prophetic example showing how to isolate the claimed DNAs might eventually lead to an actual reduction to practice, because of unpredictability in the art, those of ordinary skill in the art would not consider the inventor to have been in possession of even one species of the claimed DNAs at the time of filing.

Because the specification fails to support even one species of DNA in the claimed genus, it is apparent that a representative number of species is not disclosed.

<u>Conclusion:</u>

The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 2.

 $^{^1}$ Because the average amino acid weighs $\sim \! 110$ Da, a 22 kDa protein (like Protein A) can be predicted to be about 200 amino acids in length. Because three nucleotides are needed to code for one amino acid, a cDNA encoding Protein A would be about 600 nucleotides in length.

Case 4

[Claims]

[Claim 1] An isolated protein comprising the amino acid sequence shown in SEQ ID NO: 3. [Claim 2] An isolated variant of a protein comprising the amino acid sequence shown in SEQ ID NO: 3, wherein the variant comprises an amino acid sequence that is at least 95% identical to SEQ ID NO: 3.

[Claim 3] The isolated variant of claim 2, wherein the variant catalyzes the reaction $A \rightarrow B$.

[Description]

The description discloses a protein isolated from mouse liver that catalyzes the reaction $A \to B$. The isolated protein was sequenced and its sequence was set forth in the description as SEQ ID NO: 3. The description also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The description indicates that procedures for making proteins with substitutions, deletions, insertions and additions are routine in the art and provides an assay for detecting the catalytic activity of the protein or its variants.

Summary of Result

As for claim 1, the Trilateral Offices share the point that the requirements for disclosure and claims are met.

As for claim 2, the EPO answers that the requirements for disclosure and claims are met. On the other hand, the JPO answers that the enablement requirement and the support requirement are not met. The USPTO answers that while the written description requirement is met, the enablement requirement may not be met.

As for claim 3, the EPO and the JPO answer that the requirements for disclosure and claims are met. On the other hand, the USPTO answers that while the enablement requirement is met, the written description requirement is not met.

Answers and Comments by each Office

[Claim 1]

[EPO]

The EPO's answer is "Yes."

[JPO]

The JPO's answer is "Conditionally, yes."

The JPO interprets the invention concerning claim 1 as it being an isolated protein comprising mainly the amino acid sequence shown in SEQ ID NO: 3.

The description discloses a protein isolated from mouse liver that catalyzes the reaction $A \to B$ and its sequence. So the description is sufficient for enabling a person skilled in the art to isolate the claimed protein.

Therefore, the description satisfies the Requirement of Article 36(6)(i) and the Requirement of Article 36(4)(i).

[USPTO]

The USPTO's answer is "Yes."

35 U.S.C. 112, 1st para. The specification provides a method of making a protein comprising SEQ ID NO: 3 and describes the complete sequence of the protein.

[Claim 2] [EPO]

The EPO's answer is "Yes."

Art. 84 EPC: acceptable. Art. 83 EPC: acceptable as well, because the skilled person would know how to take 95% of SEQ ID no. 3 and modify it.

Art 84 EPC states that the European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art. The person skilled in the art is presumed to be an ordinary practitioner in a field of technology aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the "state of the art", in particular the documents cited in the search report, and to have had at his disposal the normal means and capacity for routine work and experimentation (Guidelines C-IV, 11.3). Whether the disclosure will allow the skilled man to carry out the claimed invention can only be decided on a case by case basis (long-standing practice in patent prosecution, supported by no less well-established case law).

[JPO]

The JPO's answer is "No."

The claimed variant contains the proteins which do not have the function and the part of the proteins cannot be used, and therefore, the description is not described in such a manner that enables a person skilled in the art to use the product.

Therefore, the description fails to satisfy the Requirement of Article 36(6)(i) and the Requirement of Article 36(4)(i). (See "Other Comments" below.)

In case that genes are claimed in a generic form and the function is not specified in the claim (genes specified only by "substituted, deleted or added," "hybridized" or "having more than X% identity," etc.), the genes claimed in a generic form contain the ones which do not have the said function and the part of the said genes cannot be used, and therefore, the detailed description of the invention is not described in such a manner that enables a person skilled in the art to use the product. (Examination Guidelines Part VII Chapter 2. "Biological Inventions" 1.1.2.1 (1))

[USPTO]

The USPTO's answer is "Maybe."

35 U.S.C. 112, 1st para.

The claim is directed to a variant of the protein of claim 1. While one of ordinary skill in the art would be able to make and identify variants within the scope of the claim (satisfying the written description requirement), it is not clear whether one of ordinary skill in the art would know how to use variants throughout the scope of the claim (may not satisfy the enablement requirement). (See "Other Comments" below.)

[Claim 3]

[EPO]

The EPO's answer is "Yes."

Restriction to the catalytically active members of the group in claim 2. If claim 2 is clear (see above), claim 3 is also considered to comply with Art. 84 EPC and to fulfill the requirements of Art. 83, especially if the way of testing the reaction A -> B is disclosed.

A dependent claim does not by itself define all the characterising features of the subject-matter which it claims. Consequently, where the independent claim corresponding to a dependent claim is allowable, the examiner should not concern himself unduly with the subject-matter of dependent claims, provided he is satisfied that they are truly dependent and thus in no way extend the scope of protection of the invention defined in the corresponding independent claim (Guidelines, C-III, 3.5).

[JPO]

The JPO's answer is "Yes."

Because the invention concerning claim 3 is specified by its function, the description is described in such a manner that enables a person skilled in the art to use the claimed variant.

Moreover, since the invention concerning claim 2 has similarity to SEQ ID NO:3, the

number of the proteins seems to be restricted. So the description is sufficient for enabling a person skilled in the art to obtain the variant of claim 3 from the variant of claim 2 on the basis of the function to catalyze the reaction $A \rightarrow B$ in the description.

Therefore, the description satisfies the Requirement of Article 36(6)(i) and the Requirement of Article 36(4)(i). (See "Other Comments" below and Examination Guidelines Part VII Chapter 2. "Biological Inventions" 1.1.2.1 (1).)

[USPTO]

The USPTO's answer is "No."

35 U.S.C. 112, 1st para.

While one of ordinary skill in the art would be able to make, use and identify variants within the scope of the claim (satisfying the enablement requirement), one skilled in the art would not be able to identify without further testing which of those proteins have the claimed catalytic activity (failing to meet the written description requirement). (See "Other Comments" below.)

Other Comments

[JPO]

(Claim 2) In order to satisfy the support requirement and the enablement requirement, the description shall be stated so as to enable a person skilled in the art not only to make the product but also to use the product.

The proteins which do not have the function to catalyze the reaction $A \to B$ are contained in the claimed variants specified only by the expression "wherein the variants comprise an amino acid sequence that is at least 95% identical to SEQ ID NO:3." So the claimed variant contains the proteins which do not have the function and the part of the proteins cannot be used, and therefore, the description is not stated in such a manner that enables a person skilled in the art to use the product.

In this case, not only the high similarity to SEQ ID NO: 3 but also definition by the function is needed to satisfy the support requirement and the enablement requirement. Therefore, the description fails to satisfy the support requirement (Requirement of Article 36(6)(i)) and the enablement requirement (Requirement of Article 36(4)(i)).

(Claim 3) Claim 3 is directed to the isolated variants of claim 2, wherein the variants catalyze the reaction $A \to B$. Because the invention concerning claim 3 is defined by its function, the description is stated in such a manner that enables a person skilled in the art to use the claimed variants.

Moreover, since the invention concerning claim 2 has high similarity to SEQ ID NO: 3, the number of the proteins seems to be restricted. So the description is sufficient for enabling a person skilled in the art to obtain (make) the claimed variants from the variants of claim 2 on the basis of the function to catalyze the reaction $A \rightarrow B$ without a large amount of trials and errors or complicated experimentation.

Therefore, the description satisfies the support requirement (Requirement of Article 36(6)(i)) and the enablement requirement (Requirement of Article 36(4)(i)).

[USPTO (Explanatory comments per JPO request)]

(Claim 2) The written description requirement of 35 U.S.C. 112, first paragraph requires the application to contain a written description of the invention. This requirement is separate and distinct from the enablement requirement and thus, satisfaction of one of these requirements is not conclusive with regard to the other. The written description requirement serves in part to demonstrate that a patent applicant was in possession of the invention that is claimed. In this example, the USPTO agrees with the JPO's conclusion that the enablement requirement is not met because the claimed variant includes proteins of unknown function and therefore, the description does not enable one skilled in the art to use the full scope of the claimed invention. However, in view of the disclosure of SEQ ID NO: 3, the USPTO disagrees with the JPO opinion with regard to the support requirement. Those skilled in the art could readily envision all of the amino acid sequences that are 95% identical to SEQ ID NO: 3, and recognize amino acid sequences that are 95% identical to SEQ ID NO: 3 by comparing a given sequence to SEQ ID NO: 3. Therefore, the USPTO maintains the opinion that those skilled in the art would have recognized the disclosure as showing that the applicant was in possession of the claimed genus of protein variants.

(Claim 3) The USPTO agrees that the description satisfies the enablement requirement, however under U.S. law, conclusive evidence of a claim's enablement is not equally conclusive of that claim's satisfactory written description. In this example, there is no disclosure relating similarity of structure to conservation of function. The USPTO maintains that based on the lack of knowledge and predictability in the art, those of ordinary skill in the art would not conclude that the applicant was in possession of the claimed genus of proteins (i.e., having both the claimed structure and function) based on disclosure of the single species of SEQ ID NO: 3.

[USPTO (Analysis)]

(Claim 2) Claim 2 is directed to a variant of the protein defined by claim 1 (a protein

comprising SEQ ID NO: 3), where the amino acid sequence of the variant is at least 95% identical to SEQ ID NO: 3. The claim is not limited to variants of the protein of SEQ ID NO: 3 having the function of catalyzing the reaction $A \rightarrow B$.

The specification adequately describes proteins comprising the amino acid sequence of SEQ ID NO: 3 (see the analysis of claim 1). All of the proteins within the scope of claim 2 share at least 95% of the amino acid sequence of SEQ ID NO: 3; therefore, the specification describes 95% of the structure that defines the proteins within the claimed genus. All of the species within the genus share a significant degree of partial structure (i.e., at least 95% of SEQ ID NO: 3).

The claimed variants can have amino acid substitutions, deletions, insertions, or additions, as compared to SEQ ID NO: 3. The specification does not provide an actual reduction to practice of any variants of the protein of SEQ ID NO: 3. The specification does not describe the complete structure or physical or chemical properties of any variants of SEQ ID NO: 3, although those skilled in the art would expect members of the genus to have properties similar to those of SEQ ID NO: 3, because of the high degree of structural similarity.

In view of the disclosure of SEQ ID NO: 3, those skilled in the art could readily envision all of the amino acid sequences that are 95% identical to SEQ ID NO: 3. Those skilled in the art could recognize amino acid sequences that are 95% identical to SEQ ID NO: 3 by comparing a given sequence to SEQ ID NO: 3. The presence of an amino acid sequence that is at least 95% identical to SEQ ID NO: 3 is a structural feature of each of the proteins within the claimed genus.

The level of skill and knowledge in the art is such that one of ordinary skill would be able to make and identify variants having 95% identity to SEQ ID NO: 3 routinely.

Thus, those skilled in the art would have recognized the disclosure as showing that the applicant was in possession of the claimed genus of protein variants.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 2^2 .

(Claim 3) Claim 3 is directed to the genus of variants of SEQ ID NO: 3 that comprise an amino acid sequence at least 95% identical to SEQ ID NO: 3 and catalyze the reaction A \rightarrow B.

² This example deals only with the written description analysis of the claimed method. Enablement issues that may be raised by the recited facts are not addressed here but should be considered during examination. A separate rejection for nonenablement should be made when appropriate.

The specification discloses the reduction to practice of one species within the claimed genus; specifically, the protein having the amino acid sequence of SEQ ID NO: 3. There are no drawings or structural formulas disclosed of any other proteins that catalyze the reaction $A \rightarrow B$.

The recitation of a polypeptide with at least 95% amino acid sequence identity to SEQ ID NO: 3 represents a partial structure. That is, the claimed proteins share at least 95% of the structure of SEQ ID NO: 3, while 5% of the structure can vary. There is no teaching in the specification regarding which 5% of the structure can be varied while retaining the ability of the protein to catalyze the reaction $A \rightarrow B$. Further, there is no art-recognized correlation between any structure (other than SEQ ID NO: 3) and the activity of catalyzing $A \rightarrow B$, based on which those of ordinary skill in the art could predict which amino acids can vary from SEQ ID NO: 3 without losing the catalytic activity. Consequently, there is no information about which amino acids can vary from SEQ ID NO: 3 in the claimed genus of proteins and still retain the catalytic activity.

Although the disclosure of SEQ ID NO: 3 combined with the knowledge in the art, would put one in possession of proteins that are at least 95% identical to SEQ ID NO: 3, the level of skill and knowledge in the art is such that one of ordinary skill would not be able to identify without further testing which of those proteins having at least 95% identity to SEQ ID NO: 3 (if any) have the activity of catalyzing the reaction $A \rightarrow B$. Based on the lack of knowledge and predictability in the art, those of ordinary skill in the art would not conclude that the applicant was in possession of the claimed genus of proteins based on disclosure of the single species of SEQ ID NO: 3.

Conclusion:

The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 3.

Case 5

[Claims]

[Claim 1] An isolated antibody capable of binding to antigen X.

[Description]

The description discloses that a protein designated antigen X has been isolated from HIV and is useful for detection of HIV infections. The description describes purifying antigen X by gel filtration and discloses its amino acid sequence. Antigen X is further characterized as a 55 kD monomer having no disulfide bonds, with a slightly acidic pl. The description discusses antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. However, there is no working or detailed prophetic example of an antibody that binds to antigen X.

Summary of Result

The Trilateral Offices share the point that the requirements for disclosure and claims are met.

Answers and Comments by each Office

[Claim 1]

[EPO]

The EPO's answer is "Yes." See under Case 3, claim 1.

[JPO]

The JPO considers the requirement for disclosure and claims on the presumption that "antigen X" in claim 1 is defined by specifying as a substance. (e.g. "Antigen X" in claim 1 is defined by its amino acid sequence.)

When Antigen X are known in terms of amino acid sequence and physical properties, a person skilled in the art can carry out the antibody capable of binding to the antigen X on the basis of matters described in the description taking into consideration the common general knowledge as of the filing.

Therefore, if "antigen X" in claim 1 is defined by its amino acid sequence, the description satisfies the support requirement (Requirement of Article 36(6)(i)) and the enablement requirement (Requirement of Article 36(4)(i)).

[USPTO]

The USPTO's answer is "Yes."

35 U.S.C. 112, 1st para.

The production of antibodies against a well-characterized antigen is conventional in the art, the antigen in this example is adequately described, and antibody technology is well-developed and mature.

Other Comments

As to case 5, there is no comment from the Trilateral Offices.

Case 6

[Claims]

[Claim 1] A block error compensating apparatus comprising:

a video codec decoder for decoding an inputted image frame and outputting a decoded image frame; and

an error concealment block for detecting an error-generated block in the decoded image frame, compensating the detected error block through a median filter, and outputting a compensated image frame.

[Claim 2] A block error compensating method of an image frame comprising: decoding an inputted image frame and outputting a decoded image frame; and detecting a block error of the decoded image frame, compensating the detected block error through a median filter, and outputting a compensated image frame.

[Claim 3] The method of claim 2, wherein compensating comprises:

detecting an error-generated block in the inputted image frame;

confirming whether the detected error-generated block is an error block based on a pixel value of the detected error-generated block and pixel values of blocks adjacent to the detected error-generated block;

compensating an error of the error block through a median filter to obtain a compensated block; and

restoring an image frame including the compensated block.

[Claim 4] The method of claim 3, wherein confirming is achieved by averaging pixel values of blocks adjacent to the detected block to obtain an average value, obtaining an absolute value for a difference between the average value and a pixel value of the detected block, and comparing the absolute value with a predetermined value.

[Claim 5] The method of claim 4, wherein the average value,
$$Ps(x, y)$$
, is given by
$$Ps(x,y) = [P(x-1,y-1) + P(x,y-1) + P(x+1,y-1)]/3 + [P(x-1,y) + P(x+1,y)]/2 + [P(x-1,y+1) + P(x,y+1) + P(x+1,y+1)]/3$$

wherein P(x,y) denotes a pixel value of the detected error block.

[Claim 6] The method of claim 5, wherein the average value, Pgen(x, y), is given by: Pgen (x,y) = [P(x,y-1) + P(x,y-3) + P(x+1,y-2) + P(x-1,y-2) + P(x,y+1) + P(x,y+3) + P(x+1,y+2)]/7 wherein P(x, y) denotes a pixel value of the detected error block.

[Description]

[0043],[0044] describe the formula in claim 5. However they do not explain how the filter works.

[0047] defines the median filter as a linear filter

[Conditions]

[Condition 1]

"Error generated block", claim 1 is not a concept of common use with universally accepted meaning.

[Condition 2]

[0047] describes a linear filter; this is in contradiction with claim 1 and 3 (median filter)

[Condition 3]

It is not clear how the filter defined by the formula in claims 5 and 6 works, since this is not explained in the description. No function is described for said filter

Summary of Result

The Trilateral Offices hold negative views on each condition. The JPO mentions that it depends on additional condition. The USPTO mentions that the USPTO can not answer because more information is needed.

Answer and Comments by each Office

[Condition 1]

[EP0]

The EPO's answer is "No."

"Error generated block", claim 1 is not a concept of common use with universally accepted meaning (Art. 84 EPC)

"In the context of Article 84 EPC, the meaning of a term or expression used in a feature of a claim depends in particular on the definition thereof generally accepted by those skilled in the relevant art, as established in Rule 35(12), last sentence, EPC requiring in general that use should be made of 'the technical terms... generally accepted in the field in question' " (T 728/98, pt. 3.2.1, OJ/2001, 319). NB. Rule 35(12) EPC 1973 = Rule 49(10) EPC 2000

[JPO]

The JPO's answer is "It depends on additional conditions."

If the term is defined or explained in the description, and such definition or explanation makes the claim statements clear by considering the common general knowledge as of the filing, the requirement of Article 36(6)(ii) (clarity of the invention) is met.

Where the statement in a claim are deemed unclear by itself, the examiner should examine whether a term in the claim is defined or explained in the description, and should evaluate whether such definition or explanation, if any, makes the claim statements clear by considering the common general knowledge as of the filing. If the examiner deems that an invention can be clearly identified as a result of this evaluation, the requirement of Article 36(6)(ii) (clarity of the invention) is met. (Examination Guidelines Part I Chapter 1. "Description Requirements of the Specification" 2.2.2 (4))

[USPTO]

The USPTO's answer is "Maybe."

The USPTO answer is maybe because more information is needed. The USPTO position is that a claim term would not raise clarity or definiteness issues if it is defined in the specification or if one of ordinary skill in the art would understand the meaning of the term reading the claims in light of the disclosure. See, e.g., Bancorp Services, L.L.C. v. Hartford Life Ins. Co., 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004)(holding that a claim term which was not defined or used in the specification was discernible and hence not indefinite because the reader could infer the meaning of the term with reasonable confidence).

[Condition 2]

[EPO]

The EPO's answer is "No."

[0047] describes a linear filter; this is in contradiction with claim 1 and 3 (median filter): inconsistency between description and claim (Art. 84 EPC).

Any inconsistency between the description and the claims should be avoided if it may render the claim unclear or unsupported under Art. 84 EPC, second sentence or, alternatively, render the claim objectionable under Art. 84 EPC, first sentence. (Guidelines C-III, 4-3)

[JPO]

The JPO's answer is "It does not comply with the enablement requirement."

It is clear for a person skilled in the art that "a median filter" is one of the non-linear filter and a filter which outputs the median of pixel values of adjacent blocks.

"A median filter" is generally recognized as a non-linear filter. However, "a median filter" is described as a linear filter in the description and this is contradictory to each other. Therefore, the description do not state the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person having ordinary skill in the art, even taking into consideration the common general knowledge as of the filing. It does not comply with the requirement of Article 36(4)(i) (the enablement requirement). See "Examination Guidelines Part I Chapter 1. "Description Requirements of the Specification" 2.2.2.1 (2)."

[USPTO]

The USPTO's answer is "Maybe."

Applicant is not required to explain how the invention works or the function of every component. However, it is unclear from the information provided whether one of ordinary skill in the art would have been able to make and use the claimed invention based on the disclosure.

[Condition 3]

[EP0]

The EPO's answer is "No."

It is not clear how the filter defined by the formula in claims 5 and 6 works, since this is not explained in the description (Art. 83, Art. 84 EPC); the disclosure is insufficient for the skilled person to realize the invention.

No function is described for said filter (Art.83, 84 EPC, possibly in combination with Art. 56 EPC). It is not clear which technical problem is solved and whether it is solved by the feature "filter."

It should be noted that, although an objection of lack of support is an objection under Art. 84 EPC, it can often also be considered as an objection of insufficient disclosure of the invention under Art. 83 EPC, the objection being that the disclosure is insufficient to enable the skilled person to carry out the "invention" over the whole breadth of the claim. (Guidelines, C-III, 6.4)

[JPO]

The JPO's answer is "The inventions defined by claims 5 and 6 are not clear."

Claim 6 is dependent on claim 5. However, claims 5 and 6 define "the average value" described in claim 4. Thus, "the average value" defined in claim 6 is in contradiction with "the average value" defined in claim 5. Therefore, it does not comply with the requirement of Article 36(6)(ii).

("The filter defined by the formula in claims 5 and 6" is described in "Condition 3" However, the formulas in claims 5 and 6 do not define "the filter" and define "the average value" described in claim 4, which is used to confirm "whether the detected error-generated block is an error block" in claim 3.)

[USPTO]

The USPTO's answer is "Maybe."

Applicant is not required to explain how the invention works or the function of every component. However, it is unclear from the information provided whether one of ordinary skill in the art would have been able to make and use the claimed invention based on the disclosure.

Other Comments

As to case 6, there is no comment from the Trilateral Offices.

3. Analysis of the answers

3-1. The Trilateral Offices share the following views:

(i) The Trilateral Offices share the view that if the application discloses the claimed invention in such a manner that a person skilled in the art can understand it, taking into consideration the common general knowledge as of the filing, the requirements for disclosure and claims can be satisfied. (See Case 3 and Case 5 etc.)

For example, as to results of claim 1 in Case 3, the Trilateral Offices share the view that, even when the description does not disclose the complete sequence of the protein, the requirements for disclosure and claims are satisfied since the other characteristics of the protein (e.g., its ability to bind and activate another protein, its approximate molecular weight, and the concentration of acetonitrile at which the protein will elute from a reverse phase HPLC column), a method for isolating the protein, and working example in which the protein is isolated using the disclosed method are disclosed.

As to results of Case 5, the Trilateral Offices share the view that, even when there is no disclosure of a method for production of antibodies and working examples of an antibody that binds to an antigen, the requirements for disclosure and claims are satisfied since the production of antibodies against a well-characterized antigen is conventional in the art.

(ii) The Trilateral Offices share the view that there are some cases that a claim is unclear when the term which is not a concept of common use with universally accepted meaning is used in the claim or when there is inconsistency between the term used in the claims and the term used in the description. (See Case 6.)

3-2. The Trilateral Offices have the different views as follows:

(i) As mentioned above, the Trilateral Offices share the view that if the application discloses the claimed invention in such a manner that a person skilled in the art can understand it, taking into consideration the common general knowledge as of the filing, the requirements for disclosure and claims can be satisfied. However, there are some cases that the results are different among the Trilateral Offices. (See Case 1 and Case 2.)

For example, the results of Case 1 are different among the Trilateral Offices. The EPO and the USPTO mention that the requirements for disclosure and claims are satisfied since two parameters in claim 1 are well explained and some examples and comparative examples are described. On the other hand, the JPO mentions that the requirements for disclosure and claims are not satisfied since it is not recognized that the above examples and comparative examples are fully described within an extent duly convincing a person

skilled in the art that the desired effect (performance) could be secured within the scope designated by the above parameters upon consideration of the common general knowledge at the time of filing by merely referring to the statement described in "a Detailed Description of the Invention."

The results of Case 2, which is the case that the definitions of the average diameter and the method of measuring the particles are not described, are also different among the Trilateral Offices. The EPO answers that a skilled person would probably know (from common general knowledge and/or prior art) how to measure the particles. The JPO answers that it is the common general knowledge in this field that there are several types in terms of definition and method of measuring, etc. of average size of the particles, and that the person skilled in the art does not have the same view about which type is usually used. The USPTO answers that it depends on what is already known in the art.

(ii) As to submission of later experimental evidence, the EPO answers that additional technical information cannot be filed for the purpose of sufficiency of disclosure.

The JPO answers that, in Case 1, the applicant dares to supplement the matters described in "a Detailed Description of the Invention" by submitting the experimental data after filing of the application, thereby resulting in the expansion and generalization of the matters described in "a Detailed Description of the Invention" up to the scope of the claimed invention so as to comply with the support requirements. This procedure taken by the applicant is contradictory to the intent of the patent system beyond the permissible range.

The USPTO answers that an applicant is permitted to rely upon later experimental evidence to rebut an enablement rejection and to show that the invention as claimed complied with the enablement requirement at the time the invention was made. (See Case 1.)

(iii) The Trilateral Offices have the different views on the results of claim 2 and 3 in Case 4. The Trilateral Offices answer the Case 4 on each requirement. The answers on each requirement by the Trilateral Offices are as follows:

[As to the enablement requirement]

The Trilateral Offices share the view that, in order to satisfy the enablement requirement, the invention needs to be described such a manner that a person skilled in the art can carry out (e.g., "take", "modify", "make", "use", etc.) the claimed invention.

However, the JPO and the USPTO answer that while the enablement requirement is satisfied in claim 1 and 3, it is not satisfied (or may not be satisfied) in claim 2. On the other

hand, the EPO answers that the enablement requirement is satisfied in all claims.

[As to the support requirement or the written description requirement]

The EPO answers that the enablement requirement and the support requirement are satisfied in all claims of Case 4. The JPO answers that the enablement requirement and the support requirement are satisfied in claim 1 and 3 in Case 4, the enablement requirement and the support requirement are not satisfied in claim 2 in Case 4.

On the other hand, the USPTO mentions that the written description requirement is separate and distinct from the enablement requirement, the written description requirement serves in part to demonstrate that a patent applicant was in possession of the invention that is claimed. Therefore, there is a case that the enablement requirement is satisfied but the written description requirement is not satisfied (See claim 3 in Case 4), or a case that the enablement requirement is not satisfied but the written description requirement is satisfied. (See claim 2 in Case 4.)

[As to the requirements for disclosure and claims as a whole]

The results of the Trilateral Offices in Case 4 are as follows:

The EPO answers that the requirements are satisfied in all claims.

The JPO answers that the requirements are satisfied in claim 1 and 3, however the requirements are not satisfied in claim 2 which is related to a variant of a protein not defined by its function.

The USPTO answers that the requirements are satisfied in claim 1, however the requirements are not satisfied in claim 2 and 3 which are related to a variant of a protein.

4. Appendix

[Appendix related to Case 1]

Appendix 1: Claims and Description in Case 1 Appendix 2: 2005 (Gyo-Ke) 10042 (excerption)

[Appendix related to Case 2]

Appendix 3: Claims and Description in Case 2 Appendix 4: 2004 (Gyo-Ke) 290 (excerption)