# Trilateral Project B3b

# Mutual understanding in search and examination

# Report on Comparative study on biotechnology patent practices

Theme: Comparative study on “reach-through claims”

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## 1. Introduction

A recent phenomenon in the field of biotechnology has been the filing by applicants of an increasing number of "reach-through claims," (claims to future inventions based on currently disclosed inventions). These include claims directed to candidate compounds that might be identified by using basic screening methods and to downstream uses of such candidate compounds. For example, the Offices are seeing an increasing number of applications that include claims drawn to include all the possible pharmaceutical candidate compounds identified by assaying, and claims to methods of using such candidate compounds that might be considered to be beyond the scope of the subject matter contributed by the inventor.

Given the widespread reach for downstream inventions, there is a need to compare how the patentability standards and examination strategies in the Trilateral Offices apply to these types of claims.

Based upon this need, the three Offices agreed to conduct a comparative study to enhance mutual understanding concerning the examination of "reach-through claims."

## 2. Provisions

Applicable Sections / Articles of Respective Patent Laws

| | Industrial Applicability / Utility | Enablement / Support / Sufficiency / Written Description and Clarity |
|---|---|---|
| USPTO | 101 | 112 |
| EPO | 57 | 83, 84 |
| JPO | 29 (1) | 36 (4) (6) |

**USPTO**

**35 U.S.C. § 101: Utility**

To comply with 35 U.S.C. § 101, the claimed invention must have at least one specific, substantial, and credible utility that is either asserted in the specification or is well-established.

**35 U.S.C. § 112, first paragraph: Enablement**

To comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must enable one skilled in the art to make and use the claimed invention without undue experimentation. Factors to be considered in determining whether any necessary experimentation is "undue" include the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the presence or absence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

**35 U.S.C. § 112, first paragraph: Written Description**

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, a patent specification must describe the claimed invention in sufficient detail such that one skilled in the art would reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

**35 U.S.C. § 112, second paragraph: Claim Definiteness**

To comply with the claim definiteness requirement of 35 U.S.C. § 112, second paragraph, each claim must particularly point out and distinctly claim the subject matter which the applicant regards as his or her invention. A claim is definite if one skilled in the art would be reasonably apprised of the scope of the claim when the claim is read in light of the specification.

**EPO**

**EPC Art.57: Industrial Application**

(Guidelines C-IV 4.6) "In general it is required that the description of a European patent application should, where this is not self-evident, indicate the way in which the invention is capable of exploitation in industry. In relation to sequences and partial sequences of genes this general requirement is given specific form in that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. A mere nucleic acid sequence without indication of a function is not a patentable invention..."

**EPC Art.83: Sufficiency of disclosure**

(Art.83) "The European patent application must disclose the invention in a manner

sufficiently clear and complete for it to be carried out by a person skilled in the art" (Guidelines C-II, 4.9) "The application must contain sufficient information to enable the person skilled in the art, using his common general knowledge, to perform the invention over the whole area claimed without undue burden and without needing inventive skill."

**EPC Art.84: Clarity and Support**

(Art. 84) "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description."
(Rule 29(1)) "The claims shall define the matter for which protection is sought in terms of the technical features of the invention"
(Guidelines C-III 6.3) "In order to comply with the requirement of Art. 84, there must be sufficient support of technical character in the description that allows to extend the particular teaching of the description to the whole field claimed. "

**JPO**

**Japanese Patent Law Sect. 29, First Sentence: Industrially Applicable Inventions**

(Guidelines Part VII,Chap.2, 1.3.1) "Inventions ... whose utility is not described in a specification or cannot be inferred, do not meet the requirements set forth in the first sentence in Section 29(1) of the Patent Law."

**Japanese Patent Law Sect. 36(6): Clarity of Claims**

(Guidelines Part VII, Chap. 2, 1.1.1) "According to Section 36(6)(ii) of the Patent Law, the invention for which a patent is sought shall be clear, therefore, scope of claim shall be described so that an invention is clearly identified on the basis of statements of each claim."

**Japanese Patent Law Sect. 36(4) :Description, Enablement**

(Guidelines Part VII, Chap. 2, 1.1.2.1) "Section 36(4) of the Patent Law states that "the detailed description of the invention shall be stated....in such a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art to which the invention pertains." ...For an invention of a product, the definition of "being able to carry out the invention" is to make and use the product..."

## 3. Questions

**A) Questions Common to All Cases**

1. Do the following claims satisfy clarity, enablement, support and written description requirements? If not, explain why.
2. Do the following claims satisfy the industrial applicability or utility requirements? If not, explain why.
3. If there are any comments on the kind of evidence, argument, and/or claim amendment

that may overcome any rejection for failure to satisfy the requirement of 1 and/or 2 above, please state them.

**B) The Cases**

**Case 1:**

Outline of the Specification:

The application describes the isolation of a protein (SEQ ID NO:1) which meets the novelty and inventive step (non-obviousness) requirements. Based upon the disclosed homology to known R-receptor amino acid sequences, there is no reason to doubt that the claimed receptor represents a new member of this protein family. The application further discloses that different R-receptors are important in a wide variety of physiological processes, but does not disclose any ligand for the receptor of SEQ ID NO: 1 or any particular biological or biochemical process in which this receptor is involved.

The patent application specification includes a general description of a series of screening procedures commensurate in scope with those recited in the claim. However, the application discloses no working examples wherein agonists of this receptor, i.e., compounds activating this receptor, are identified using the disclosed screening procedure.

Furthermore, although the receptor of SEQ ID NO: 1 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 1.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
   preparing a candidate compound,
   contacting a cell which expresses said receptor on its surface with said candidate compound, and
   determining whether said candidate compound activates the receptor of claim 1,
   wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

3. An isolated and purified receptor agonist identified by the method of claim 2.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2.
   (USPTO) A method for the treatment of disease treatable by the agonist of claim 2, comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
   (JPO) Composition comprising a receptor agonist for use in treating a disease treatable

by said agonist, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

5. A monoclonal antibody which recognizes the receptor of claim 1.

**Case 2**

Outline of Specification:

The application describes the isolation of a receptor (SEQ ID NO: 2) which meets the novelty and inventive step (non-obviousness) requirements as well as methods of screening for compounds that activate this receptor. The application further discloses that the receptor is useful for the treatment of obesity.

The relationship between the absence of this receptor and the occurrence of obesity is determined by experimental measures, and there is no doubt that the activation of this receptor can treat or inhibit obesity.

The patent application specification includes a general description of a series of screening procedures commensurate in scope with those recited in the claims. The description also teaches a method of measuring the biochemical and binding activity of this specific receptor, and there is no doubt that these activities can be measured. However, the application discloses no working examples wherein agonists of this receptor, i.e., compounds activating this receptor, are identified using the disclosed screening procedure.

Furthermore, although the receptor of SEQ ID NO: 2 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 2.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
preparing a candidate compound,
contacting a cell which expresses said receptor on its surface with said candidate compound, and
determining whether said candidate compound activates the receptor of claim 1,
wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

3. An isolated and purified receptor agonist identified by the method of claim 2.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for inhibiting obesity, wherein said receptor agonist is identified by the method of claim 2.
(USPTO) A method for the treatment of obesity, comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
(JPO) Composition comprising a receptor agonist for use in treating obesity, wherein

said receptor agonist is identified by the method of claim 2, as an active ingredient.

5. A monoclonal antibody which recognizes the receptor of claim 1.

**Case 3**

Outline of Specification:

The application describes the isolation of a protein (SEQ ID NO: 3) which meets the novelty and inventive step (non-obviousness) requirements. Based upon the disclosed homology to known R-receptor amino acid sequences, there is no reason to doubt that the claimed receptor represents a new member of this protein family. The application describes methods of screening for compounds that activate this receptor. The application further discloses that different R-receptors are important in a wide variety of physiological processes, but does not disclose any particular biological or biochemical process in which this receptor is involved, except that its activation induces a cascade of second-messenger signals, similar to that of a G-protein coupled receptor.

The patent application specification includes a specific description of a series of screening procedures commensurate in scope with those recited in the claims. In particular, there is a description of a method of identifying or screening for agonists of this receptor, i.e., compounds that activate the claimed receptor, wherein the activated state is detected when a cascade of second-messenger signals occurs. There is no doubt that the skilled artisan could use the claimed R-receptor to identify (find) agonists.

In addition, the application discloses three working examples wherein compounds activating this receptor, namely X, Y, and Z were identified using the disclosed screening procedure.

The application provides no structural information for compounds other than X, Y, or Z or methods of making compounds other than X, Y, or Z.

Furthermore, although the receptor of SEQ ID NO: 3 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 3.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
   preparing a candidate compound,
   contacting a cell which expresses said receptor on its surface with said candidate compound, and
   determining whether said candidate compound activates the receptor of claim 1,
   wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

3. An isolated and purified receptor agonist identified by the method of claim 2.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for treating a

disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2.
(USPTO) A method for the treatment of disease treatable by the agonist of claim 2, comprising administering to a host in need thereof a therapeutically effective amount of the agonist of claim 3.
(JPO) Composition comprising a receptor agonist for use in treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

5. (EPO) Use of compound X for the manufacture of a medicament for treating a disease treatable by said compound.
(USPTO) A method for treating a disease treatable by compound X comprising administering to a host in need thereof a therapeutically effective amount of compound X.
(JPO) Composition comprising compound X for use in treating a disease treatable by said compound, as an active ingredient.

6. A monoclonal antibody which recognizes the receptor of claim 1.

**Case 4:**

Outline of Specification:

The application describes the isolation of a receptor (SEQ ID NO: 4) which meets the novelty and inventive step (non-obviousness) requirements as well as methods of screening for compounds that activate this receptor. The application further discloses that the receptor is useful for the treatment of obesity.

The patent application specification includes a specific description of a series of screening procedures commensurate in scope with those recited in the claims.

In addition, the application discloses three working examples wherein agonists of this receptor, i.e., compounds activating this receptor, namely X, Y, and Z were identified using the disclosed screening procedure.

Furthermore, the pharmacological mechanism involved in the treatment or inhibition of obesity by the activation of this receptor is described theoretically in the specification.

In addition, *in vivo* test data confirms that at least compound X is able to activate this receptor when administered to a host animal and such administration results in a reduction in total body weight of an art recognized model for obesity.

The application provides no structural information for compounds other than X, Y, or Z or methods of making compounds other than X, Y, or Z.

Furthermore, although the receptor of SEQ ID NO: 4 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 4.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
   preparing a candidate compound,
   contacting a cell which expresses said receptor on its surface with said candidate compound, and
   determining whether said candidate compound activates the receptor of claim 1,
   wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

3. An isolated and purified receptor agonist identified by the method of claim 2.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for inhibiting obesity, wherein said receptor agonist is identified by the method of claim 2.
   (USPTO) A method for the treatment of obesity comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
   (JPO) Composition comprising a receptor agonist for use in treating obesity wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

5. (EPO) Use of compound X for the manufacture of a medicament for inhibiting obesity.
   (USPTO) A method for the treatment of obesity comprising administering to a host in need thereof a therapeutically effective amount of compound X.
   (JPO) Composition comprising compound X for use in treating obesity, as an active ingredient.

6. A monoclonal antibody which recognizes the receptor of claim 1.

**C) Summary of the Cases**

| | Case 1 | Case 2 | Case 3 | Case 4 |
|---|---|---|---|---|
| Method used to support asserted function of receptor | homology search methods | experimental methods | homology search methods | experimental methods |
| Knowledge of the relationship between receptor and a specific disease (biological function) | unknown | confirmed | unknown | confirmed |
| Working example of claimed screening method | none | none | described | described |
| Receptor protein | claim 1 | claim 1 | claim 1 | claim 1 |
| Screening method | claim 2 | claim 2 | claim 2 | claim 2 |
| Receptor agonist (activating compound) | claim 3 | claim 3 | claim 3 | claim 3 |
| Medical application of receptor agonists (activating compounds) in general :Pharmaceutical compositions, methods for treatment, or uses for the manufacture of a medicament | claim 4 | claim 4 | claim 4 | claim 4 |

| | | | | |
|---|---|---|---|---|
| Medical application of defined receptor agonists (activating compounds) :Pharmaceutical compositions, methods for treatment, or uses for the manufacture of a medicament | | | claim 5 | claim 5 |
| Monoclonal antibody which recognizes receptor | claim 5 | claim 5 | claim 6 | claim 6 |

## 4. Summary of Answers

**A) Receptor Proteins (Claim 1 of Cases 1 - 4)**

**Industrial Applicability (Application) / Utility**

The three Offices concluded that there was no industrial applicability (application)/utility for claim 1 in Cases 1 and 3. The amino acid sequences of the Cases are not assigned to a particular (specific) function, i.e., there is no indication of a specific and substantial use for the protein, and therefore the claim does not comply with industrial applicability (application)/utility.

For Cases 2 and 4, the receptor is useful in diagnostic methods relating to obesity, and therefore, complies with industrial applicability (application) and utility.

**Enablement / Support / Clarity and/or Written Description**

The three Offices concluded that for all Cases, the claim is clear, since the receptor is defined by an amino acid sequence, and since the sequence is specifically disclosed.
The three Offices concluded that in all the Cases, the person skilled in the art (skilled artisan) can understand "how to make" (prepare) the protein.
However, in Cases 1 and 3, since the specific function of the receptor has not been disclosed, it would require undue experimentation (or be an undue burden) for the person skilled in the art, to understand "how to use" the receptor (or perform the invention over its entire scope), and thus, claim 1 in these Cases lack enablement.

The three offices concluded that in Cases 2 and 4, the claim meets the requirement of enablement, support, clarity, and/or written description.

**Other Comments**

(EPO) Case 1: No obvious possibility to overcome all the objections above. (Amendments are likely to violate Art. 123 (2) EPC.)
Case 3: No obvious possibility to overcome objection, unless in the context of compounds X, Y, Z there is a more concrete indication of function.
Cases 1 and 3: Objections are also made on the basis of lack of inventive step. Prima facie, the routine provision of further sequences having the same gener-

al function as the known prior art sequences of closely related structure is not inventive. The structural non-obviousness is not a reason to accept an inventive step; sequences as well as all chemical compounds should solve a technical problem in a non-obvious manner to be recognized as inventive. (As a consequence, inventive step of claims 2 and 6 of Cases 1 and 3 are also denied.)

(USPTO) Cases 1 and 3: Objective evidence might overcome rejection for utility if it supports an assertion that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity.

(JPO) Case 1 and 3: No obvious possibility to overcome reason for refusal, at least for lack of enablement.

**B) Screening Methods (Claim 2 of Cases 1 - 4)**

**Industrial Applicability (Application) / Utility**

The three Offices concluded that claim 2 does not meet industrial applicability (application)/utility in Cases 1 and 3, since there can be no industrial applicability (application)/utility for methods of identifying agonists that are asserted to stimulate an unknown function.

However, claim 2 does meet the requirements in Cases 2 and 4, since the claimed methods for identifying agonists are industrially applicable/useful in view of the proven pharmaceutical relevance of the receptor.

**Enablement / Support / Clarity and/or Written Description**

For Cases 1 and 3, the three Offices concluded that the claim does not comply with enablement, support, clarity, and/or written description.

For Cases 1 and 3, the Trilateral Offices concluded that since the specification does not provide any guidance with respect to the activity of the receptor, nor any working examples, the person skilled in the art cannot use the claimed assay without undue experimentation. Since the description does not describe how the "agonist compound" can be used, the claim lacks enablement. For Case 3, however, the EPO stated that the objection should preferably be made under "lack of inventive step."

For Case 1, the Trilateral Offices concluded that the claim does not comply with written description (USPTO), or is not sufficiently supported by the description (EPO), or is unclear (JPO), since the method of analyzing any activity of the receptors is unclear to the person skilled in the art.

However, for Case 3, the three Offices concluded that the requirement for an adequate written description (USPTO), or clarity and support (EPO), or clarity of claims (JPO) is

met because the specification teaches methods of screening for compounds that activate this receptor and thus one skilled in the art would conclude that the applicant was in possession of such methods. Furthermore, the “how to make” prong of the enablement requirement of 35 U.S.C. § 112, first paragraph is met since the specification specifically teaches methods of screening for compounds that activate the claimed receptor of claim 1.

For Cases 2 and 4, the three Offices concluded that the claim complies with enablement, support, clarity, and/or written description.
The specification in Case 4 discloses methods of screening for compounds that activate this receptor as well as working examples, and the receptor’s activity is disclosed. The description also teaches the relationship of the receptor with a specific disease, i.e. obesity. Therefore, the requirements of enablement, support, clarity, and/or written description are met.
In Case 2, the description provides general reference toward standard screening methods. Although the description does not provide working examples, the description teaches a method for measuring the biochemical and binding activity of the specific receptor, and the person skilled in the art can understand how to use the screening method considering the common general knowledge. Therefore, the requirements of enablement, support, clarity, and/or written description are met as well.

**Other Comments**

(EPO) Cases 1 and 3: No obvious possibility to overcome all the rejections above. (Amendments are likely to violate Art.123 (2) EPC.)

(USPTO) Cases 1 and 3:Objective evidence might overcome rejection for utility if it supports an assertion that one of ordinary skill in the art would recognize a specific, substantial, and credible utility for the agonist, or "how to use" the agonist, identified by the claimed method.

(JPO) Cases 1 and 3: No obvious possibility to overcome reason for refusal, at least for lack of enablement.

## C) Agonists (Activating Compounds) Identified by the Screening Method Of Claim 2, and Medical Application of Agonists (Activating Compounds) of Claim 3 (Claim 3 & 4 of Cases 1 - 4)

**Industrial Applicability (Application) / Utility**

The three Offices concluded that in Cases 1 and 3, industrial applicability (application)/ utility is not met for the same reason as discussed for claims 1 and 2.

The three Offices also concluded that for Case 4, industrial applicability (application)/ utility is met for the same reason as discussed for claims 1 and 2.

As for Case 2, the JPO and USPTO concluded that the claim complies with industrial applicability (application)/ utility, for the same reason as discussed for claims 1 and 2. The EPO concluded that although it can be said that a compound that has not been disclosed cannot be made and used in any kind of industry, it can also be argued that the person skilled in the art would know that there is a potential application for agonists in the treatment of obesity. The question "Industrial application, yes or no" has however no practical relevance in this case, since the Lack of Support is so striking.

**Enablement / Support / Clarity and/or Written Description**

The three Offices concluded that except for compounds X, Y and Z in Case 4, the general scope of claims 3 and 4 in Cases 1-4 do not comply with enablement, support and/or written description requirements. The claims encompass a genus of compounds defined only by their function wherein the relationship between the structural features of the members of the genus and said function have not been defined. In the absence of such a relationship either disclosed in the as-filed application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound (other than those that might be particularly disclosed in an application) would fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity.

In Cases 1 and 3, where the specific function (e.g., its relationship to a specific disease) of a receptor is not disclosed, claim 4 referring to a "disease treatable by the agonist" of the said receptor is unclear.

**Other Comments**

(EPO) All Cases: The claim will be objected at the search stage, and no search will be carried out for compounds which are only defined by the method for their identification.

Cases 1, 2, and 3: No obvious possibility to overcome the rejections above.

Cases 4: Possibilities to overcome the rejections above: restriction to X,Y,Z.

(USPTO)Case 1 and 3 (Claim 4-Utility): Objective evidence might overcome rejection of utility, if it supports an assertion that one of the ordinary skill in the art would have known what disease(s) would have been treatable with the undisclosed agonist.

Case 3 (Claim 3-Utility): The rejection for lack of utility in claim 3 might be overcome with a showing of objective evidence that supports the position that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a par-

ticular specific and substantial function or activity, or that a specific and substantial purpose for agonizing such function would have been known to those of skill in the art.

Cases 3 and 4 (Claim 3-Written description): The written description rejection might be overcome by showing of objective evidence that supports the proposition that the particularly disclosed receptor agonists were representative of the structure of the group of molecules that would be detected or identified by the claimed method. The written description rejection may also be overcome by limiting the scope of the claim in each Case to the specifically disclosed agonists (X, Y, and Z).

Case 4 (Claims 3 and 4 – Written description and enablement): The written description and enablement rejections may be overcome by limiting the scope of the claimed agonists to X, Y, and Z.

(JPO) Cases 1, 2 and 3: No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Case 4: A restriction of the agonists (activating compounds) to the compounds which can be made by the person skilled in the art according to the description and considering the common general knowledge at the time of filing, would overcome the reason for refusal concerning lack of enablement. However, amendments must be made within the scope of the original specification (Patent Law Sec.17 bis).

Restriction to compounds X,Y,Z, which can be made by the person skilled in the art according to the description and considering the common general knowledge, will overcome the reasons for rejection above in Case 4.

## D) Medical Application of Specific Compounds Identified by the Screening Methods: Pharmaceutical Compositions, Methods for Treatment, or Use for the Manufacture of Medicaments (Claim 5 of Cases 3 & 4)

### Industrial Applicability (Application) / Utility

In Case 3, the three Offices concluded that unless a specific disease is known, the claim relating to the treatment of the disease do not fulfil the requirements of industrial applicability (application) / utility.

In Case 4, the three Offices concluded that since the claim is drawn to the treatment of a particular disease, the claim complies with industrial applicability (application) / utility.

### Enablement / Support / Clarity and/or Written Description

In Case 3, the Trilateral Offices concluded that unless a specific disease is known, the claim relating to the treatment of the disease is unlikely to fulfil the requirements of enablement, support, clarity, and/or written description.

In Case 4, the claim fulfils the requirements of enablement, support, clarity, and/or written description, since the claimed invention is drawn to treating is a specific disease using specific and disclosed compounds, the person skilled in the art can understand how to make and use the invention, and there is no reason to doubt the effect of the compound.

**E) Monoclonal Antibodies Which Recognize the Claimed Receptor (Claim 5 of Cases 1 & 2, Claim 6 of Cases 3 & 4)**

**Industrial Applicability (Application) / Utility**

The three Offices concluded that for Cases 1 and 3, claim 5(or 6) does not comply with industrial applicability and utility requirements, but for Cases 2 and 4, the claim does comply with the said requirements, for the reasons stated for claim 1.

**Enablement / Support / Clarity and/or Written Description**

The three Offices concluded that the claim complies with clarity, and/or written description, for Cases 1-4. Monoclonal antibodies are traditionally defined by their target (i.e., its antigen), so the claim is usually clear to the person skilled in the art, and in view of the manner in which antibodies are made, it is also generally accepted that if one is in possession of any particular protein sequence, one would also have been “in possession” of its antibody.

The claim complies with enablement and/or support requirements in Case 2 and 4, since the person skilled in the art could obtain a monoclonal antibody specific to a given protein, using routine and well known methods, and use the antibodies in diagnostic methods.

The three Offices concluded that for Cases 1 and 3, the claim does not comply with enablement / support, since although the person skilled in the art can make the antibody using routine procedures, it would require undue experimentation (or be an undue burden) for the person skilled in the art to determine the specific function of the antibody and thus determine how to use the antibody.

**Other Comments**

See the comments in "A) Receptor Proteins (Claim 1 of Cases 1 - 4)."

(EPO) In cases where the receptor families are of closely related structure, it may become necessary to restrict the scope of the present claims to specific antibodies, in order to distinguish these antibodies from potentially existing prior art antibodies against the related receptors and thereby overcoming a possible novelty objection. However, attention must be paid that in the present Cases, there seems to be no basis in the description as filed for such an amendment.

## F) Summary of Answers

**(In the following answers, Y stands for 'Yes', N stands for 'No')**

**USPTO**

| Case | Claim | Utility | Written Description | Enablement | |
|---|---|---|---|---|---|
| | | | | "How to Make" | "How to Use" |
| 1 | 1 | N | Y | Y | N |
| | 2 | N | N | N | N |
| | 3 | N | N | N | N |
| | 4 | N | N | N | N |
| | 5 | N | Y | Y | N |
| 2 | 1 | Y | Y | Y | Y |
| | 2 | Y | Y | Y | Y |
| | 3 | Y | N | N | N |
| | 4 | Y | N | N | N |
| | 5 | Y | Y | Y | Y |
| 3 | 1 | N | Y | Y | N |
| | 2 | N | Y | Y | N |
| | 3 | N | N/Y (scope) | N/Y (scope) | N |
| | 4 | N | N | N | N |
| | 5 | N | N | N | N |
| | 6 | N | Y | Y | N |
| 4 | 1 | Y | Y | Y | Y |
| | 2 | Y | Y | Y | Y |
| | 3 | Y | N/Y (scope) | N/Y (scope) | N/Y (scope) |
| | 4 | Y | N/Y (scope) | N/Y (scope) | N/Y (scope) |
| | 5 | Y | Y | Y | Y |
| | 6 | Y | Y | Y | Y |

**EPO**

| Case | Claim | Industrial Applicability | Clarity/Support | Sufficiency |
|---|---|---|---|---|
| 1 | 1 | N | Y | Y/N* |
| | 2 | N | Y/N | N |
| | 3 | N | N | N |
| | 4 | N | N | N |
| | 5 | N | Y | Y/N* |
| 2 | 1 | Y | Y | Y |
| | 2 | Y | Y | Y |
| | 3 | Y | N | N |
| | 4 | Y | N | N |
| | 5 | Y | Y | Y |
| 3 | 1 | N | Y | Y/N* |
| | 2 | N | Y | Y/N* |
| | 3 | N | N | N |
| | 4 | N | N | N |
| | 5 | N | N | N |
| | 6 | N | Y | Y/N* |

| | | | | |
|---|---|---|---|---|
| 4 | 1 | Y | Y | Y |
| | 2 | Y | Y | Y |
| | 3 | Y | Y/N (scope) | Y/N (scope) |
| | 4 | Y | Y/N (scope) | Y/N (scope) |
| | 5 | Y | Y | Y |
| | 6 | Y | Y | Y |

*debatable whether it would be an undue burden to perform the invention over the whole area, since the specific function of receptor has not been disclosed; it is, however, a problem that should be dealt with under "lack of inventive step."

**JPO**

| Case | Claim | Industrial Applicability | Clarity | Enablement |
|---|---|---|---|---|
| 1 | 1 | N | Y | N |
| | 2 | N | N | N |
| | 3 | N | N | N |
| | 4 | N | N | N |
| | 5 | N | Y | N |
| 2 | 1 | Y | Y | Y |
| | 2 | Y | Y | Y |
| | 3 | Y | N | N |
| | 4 | Y | N | N |
| | 5 | Y | Y | Y |
| 3 | 1 | N | Y | N |
| | 2 | N | Y | N |
| | 3 | N | N | N |
| | 4 | N | N | N |
| | 5 | N | N | N |
| | 6 | N | Y | N |
| 4 | 1 | Y | Y | Y |
| | 2 | Y | Y | Y |
| | 3 | Y | N | N* |
| | 4 | Y | N | N* |
| | 5 | Y | Y | Y |
| | 6 | Y | Y | Y |

* to the general scope of the claim

## 5. Conclusion

### Summary of Comments: Fulfillment of Requirements of Industrial Applicability, Utility, Enablement, Support, Clarity and/or Written Description

(For the following chart, 'Y' means all the above requirements are met, whereas 'N' means more than one of the requirements are not met, considering the general scope of the claims.)

| Case | Claim | USPTO | EPO | JPO |
|---|---|---|---|---|
| 1 | 1 | **N** | **N** | **N** |
| | 2 | **N** | **N** | **N** |
| | 3 | **N** | **N** | **N** |
| | 4 | **N** | **N** | **N** |
| | 5 | **N** | **N** | **N** |
| 2 | 1 | **Y** | **Y** | **Y** |
| | 2 | **Y** | **Y** | **Y** |
| | 3 | **N** | **N** | **N** |
| | 4 | **N** | **N** | **N** |
| | 5 | **Y** | **Y** | **Y** |
| 3 | 1 | **N** | **N** | **N** |
| | 2 | **N** | **N** | **N** |
| | 3 | **N** | **N** | **N** |
| | 4 | **N** | **N** | **N** |
| | 5 | **N** | **N** | **N** |
| | 6 | **N** | **N** | **N** |
| 4 | 1 | **Y** | **Y** | **Y** |
| | 2 | **Y** | **Y** | **Y** |
| | 3 | **N** | **N** | **N** |
| | 4 | **N** | **N** | **N** |
| | 5 | **Y** | **Y** | **Y** |
| | 6 | **Y** | **Y** | **Y** |

The three Offices shared the following views:

1. In cases where the specific function (e.g., the relationship to a specific disease) of a receptor protein is not disclosed, the claims for:
   (1) the receptor
   (2) screening methods using said receptor
   (3) agonists (activating compounds) in general identified by said screening methods
   (4) methods, uses, or medicaments utilizing said agonists (activating compounds) in general
   (5) methods, uses, or medicaments utilizing the specific agonists (activating compounds) and
   (6) monoclonal antibodies which recognize the receptor

   do not comply with one or more of the requirements of industrial applicability (application), utility, enablement, support, clarity, and/or written description

2. In cases where the specific function (e.g., the relationship to a specific disease) of a receptor is disclosed, claims for:
   (1) the receptor

   meet all the requirements of industrial applicability (application), utility, enablement, support, clarity and written description.

   In such case, claims for:

(2) screening methods using said receptor

meet all the requirements of industrial applicability (application), utility, enablement, support, clarity and written description if:

(a) there is a working example of the screening method, or

(b) there is a general reference to standard screening methods that can be applied with a reasonable expectation of success, together with the disclosure of a method for measuring the biochemical and binding activity of the specific receptor, or

(c) the person skilled in the art can understand how to use the screening method, considering the common general knowledge.

3. Regardless of whether the specific function (e.g., the relationship to a specific disease) of a receptor protein is disclosed, the claims for:

(3) agonists (activating compounds) in general identified by said screening methods and

(4) methods, uses, or medicaments utilizing said agonists (activating compounds) in general

do not meet enablement and/or support requirements, considering the general scope of the claims. The claims encompass a genus of compounds defined only by their function wherein the relationship between the structural features of the members of the genus and said function have not been defined. In the absence of such a relationship either disclosed in the as-filed application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound (other than those that might be particularly disclosed in an application) would fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity.

4. In cases where the specific function (e.g., the relationship to a specific disease) of a receptor protein is disclosed, and specific agonists (activating compounds) are identified (found) by screening methods using said receptor, the claims for:

(5) methods, uses, or medicaments utilizing the specific agonists (activating compounds)

meet all the requirements of industrial applicability (application), utility, enablement, support, clarity and written description as long as there is adequate guidance with respect to how such uses would be put into effect. Furthermore, claims limited to the specific agonists identified (found) by the screening method using the receptor would meet all the requirements of industrial applicability (application), utility, enablement, support, clarity and written description if the agonists could be made by the person skilled in the art in view of the description in the specification and the common general knowledge in the art.

5. In cases where the specific function (e.g., the relationship to a specific disease) of a receptor protein is disclosed, the claims for:
   (6) monoclonal antibodies which recognize the receptor
   meet all the requirements of industrial applicability (application), utility, enablement, support, clarity and written description if the receptor is clearly described.