

1. Summary of the Comments of the JPO

		Case 1	Case 2	Case 3	Case 4
Method used in considering function of receptor		based on homology search methods	based on experimental methods	based on homology search methods	based on 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	Clarity	yes	yes	yes	yes
	Enablement	no	yes	no	yes
	Industrial Applicability	no	yes	no	yes
Screening method	Clarity	no	yes	yes	yes
	Enablement	no	yes	no	yes
	Industrial Applicability	no	yes	no	yes
Receptor agonist (activating compound)	Clarity	no	no	no	no
	Enablement	no	no	no	no
	Industrial Applicability	no	yes	no	yes
Pharmaceutical composition comprising receptor agonist (activating compound)	Clarity	no	no	no	no
	Enablement	no	no	no	no
	Industrial Applicability	no	yes	no	yes
Pharmaceutical composition comprising specific agonist (activating compound)	Clarity			no	yes
	Enablement			no	yes
	Industrial Applicability			no	yes
Monoclonal antibody recognizing receptor	Clarity	yes	yes	yes	yes
	Enablement	no	yes	no	yes
	Industrial Applicability	no	yes	no	yes

2. Detailed Comments

Case 1

Claim 1 [Receptor protein]

Q1) [Clarity: Yes] The receptor is specified by its amino acid sequence, and therefore is clear.

[Enablement: No] Even if the claimed receptor, from its homology to known R-receptor amino acid sequences, is considered to belong to the R-receptor family, the person skilled in the art could still not understand the relationship between the claimed receptor and any specific biological function or disease, even upon consideration of common general technical knowledge.

Therefore, the claim lacks enablement, since the person skilled in the art could not understand "how to use" the receptor. It would require undue experimentation to perform such an invention.

Q2)[Industrial Applicability: No] The claim lacks industrial applicability, since the application does not indicate how the receptor is industrially applied.

Q3)[Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 2 [Screening method]

Q1)[Clarity: No] The claim lacks clarity, since the specification only gives a vague and general description of screening procedures, and it is unclear to the person skilled in the art, whatever conceivable changes in the experimental system would be available as the criteria of judgement, in choosing a receptor agonist (activating compound), even taking into consideration common general technical knowledge.

[Enablement: No] The claim lacks enablement as well, since the person skilled in the art, cannot understand, and therefore cannot use the above criteria of judgement, in choosing a receptor agonist (activating compound), even taking into consideration common general technical knowledge.

Furthermore, the claim lacks enablement from a different viewpoint, because in this case, the specific function of the claimed receptor is unknown, and therefore the person skilled in the art cannot easily understand the how to actually use any screening method utilizing said receptor. It would require undue experimentation to perform such an invention.

Q2)[Industrial Applicability: No] The claim also lacks industrial applicability, since the application does not disclose how to apply the receptor in an industrial way.

Q3)[Other Comments] No obvious possibility to overcome reason for refusal, at least for

lack of enablement.

Claim 3 [Receptor agonist (activating compound)]

Q1)[Clarity: No] The claim lacks clarity, since the agonist is a compound specified by its function or property, and we cannot say that the person skilled in the art can easily formulate a specific compound from its function or property, even upon consideration of common general technical knowledge.

[Enablement: No] The claim lacks enablement, since the application does not disclose a specific use of the compound, and the person skilled in the art cannot know "how to use" it.

Furthermore, the claim also lacks enablement because there is no disclosure of specific chemical structures, which may be obtained through working examples, or any other matter which would serve as a clue to obtain such a compound. There is neither any support to whether such compound is actually obtainable. It would require undue experimentation to perform such an invention.

Q2)[Industrial Applicability: No] The claim also lacks industrial applicability, since the application does not disclose how to apply the receptor agonist (activating compound) in an industrial way.

Q3)[Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 4 [Pharmaceutical composition comprising receptor agonist (activating compound)]

Q1)[Clarity: No] The claim lacks clarity, because when the receptor agonist (activating compound) is unclear, a pharmaceutical composition comprising such agonist (activating compound) would also become unclear.

[Enablement: No] The claim also lacks enablement, because the person skilled in the art cannot understand how to obtain a specific agonist (activating compound), and what sort of disease-treating composition the compound should be used to manufacture, even upon consideration of general common technical knowledge. It would require undue experimentation to perform such an invention.

Q2)[Industrial Applicability: No] If the person skilled in the art cannot understand how to industrially apply the receptor agonist (activating compound), he/she could not understand how to industrially apply a pharmaceutical composition comprising said agonist (activating compound). Thus, the claim lacks industrial applicability.

Q3) [Other Comments] See comments concerning claim 3.

Claim 5 [Anti-receptor monoclonal antibody]

Q1)[Clarity: Yes] The claimed monoclonal antibody is specified by the antigen it recognizes. This is a common way to specify a subject matter in this technical field. Therefore, if the antigen is clear, a monoclonal antibody specified by the antigen is also considered clear.

[Enablement: No] Since the person skilled in the art cannot understand how to use the receptor, he/she also cannot understand how to use a monoclonal antibody recognizing the receptor, and thus, the claim lacks enablement .

Q2)[Industrial Applicability: No] Since the claim for the receptor lacks industrial applicability, a monoclonal antibody recognizing the receptor also violates the same requirement.

Case 2

Claim 1 [Receptor protein]

Q1)[Clarity: Yes] The receptor is specified by its amino acid sequence, and therefore is clear.

[Enablement: Yes] The specification discloses the relationship between the receptor and a specific disease, and therefore, a use, such as an antigen to produce diagnostic antibodies can be recognized to the person skilled in the art. Therefore, the person skilled in the art can understand how to use the receptor. Furthermore, since the receptor is actually produced, it is assumed to be obtainable by conventional methods. Therefore, the claim complies with the enablement requirement.

Q2)[Industrial Applicability: Yes] The claim also meets industrial applicability, since the person skilled in the art can recognize a way to industrially apply the receptor.

Claim 2 [Screening method]

Q1)[Clarity: Yes] In this case, 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 what is claimed.

[Enablement: Yes] The claim complies with enablement, since the person skilled in the art can understand how to perform the screening method, since the description teaches a method for measuring the biochemical and binding activity of the specific receptor.

Q2)[Industrial Applicability: Yes] The claim meets industrial applicability, since if there would be such a screening method, it would be useful for the discovery of a novel anti-obesity compound.

Claim 3 [Receptor agonist (activating compound)]

Q1)[Clarity: No] The claim lacks clarity, since the agonist is a compound specified by its function or property, and we cannot say that the person skilled in the art can easily formulate a specific compound from its function or property, even upon consideration of common general technical knowledge.

[Enablement: No] The claim also lacks enablement because there is no disclosure of specific chemical structures, which may be obtained through working examples, or any other matter which would serve as a clue to obtain such a compound. There is neither any support to whether such compound is actually obtainable. It would require undue experimentation to perform such an invention.

Q2)[Industrial Applicability: Yes] The claim meets industrial applicability, since if there would be such an agonist (activating compound), it would be useful for the manufacture of a novel anti-obesity drug.

Q3)[Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 4 [Pharmaceutical composition comprising receptor agonist (activating compound)]

Q1)[Clarity: No] The claim lacks clarity, because when the receptor agonist (activating compound) is unclear, a pharmaceutical composition comprising such agonist (activating compound) would also become unclear.

[Enablement: No] The claim also lacks enablement, because the person skilled in the art cannot understand how to obtain a specific agonist (activating compound), even upon consideration of general common technical knowledge. It would require undue experimentation to perform such an invention.

Q2)[Industrial Applicability: Yes] The application discloses that the composition can be used as an anti-obesity drug, and therefore is industrially applicable.

Claim 5 [Anti-receptor monoclonal antibody]

Q1)[Clarity: Yes] The claimed monoclonal antibody is specified by the antigen it recognizes. This is a common way to specify a subject matter in this technical field. Therefore, if the antigen is clear, a monoclonal antibody specified by the antigen is also considered clear.

[Enablement: Yes] If an antigen protein is obtainable, a monoclonal antibody that simply recognizes the antigen is also considered obtainable, using conventional methods. And if the person skilled in the art can understand how to make and use the receptor, he/she can also understand how to use a monoclonal antibody recognizing the receptor. In this case, both requirements are met, and thus, the claim meets

enablement.

Q2)[Industrial Applicability: Yes] Since the claim for the receptor meets industrial applicability, a monoclonal antibody recognizing the receptor also meets the same requirement.

Case 3

Claim 1 [Receptor protein]

Q1)[Clarity: Yes] The receptor is specified by its amino acid sequence, and therefore is clear.

[Enablement: No] Even if the claimed receptor, from its homology to known R-receptor amino acid sequences, is considered to belong to the R-receptor family, the person skilled in the art could still not understand the relationship between the claimed receptor and any specific biological function or disease, even upon consideration of common general technical knowledge.

Therefore, the claim lacks enablement, as the person skilled in the art could not understand "how to use" the receptor. It would require undue experimentation to perform such an invention.

Q2)[Industrial Applicability: No] The claim lacks industrial applicability, since the application does not indicate how the receptor is industrially applied.

Q3)[Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 2 [Screening method]

Q1)[Clarity: Yes] The claim meets clarity, since it is clear to the person skilled in the art, based on the working example described in the application, whatever conceivable changes in the experimental system would be available as the criteria of judgement, in choosing a receptor agonist (activating compound).

[Enablement: No] The person skilled in the art can understand, based on the working example described in the application, whatever conceivable changes in the experimental system would be available as the criteria of judgement, in choosing a receptor agonist (activating compound).

However, the claim lacks enablement, because in this case the specific function of the claimed receptor is unknown, and therefore the person skilled in the art cannot easily understand how to actually use any screening method utilizing said receptor. It would require undue experimentation to perform such an invention.

Q2)[Industrial Applicability: No] The claim also lacks industrial applicability, since the

application does not disclose how to apply the receptor in an industrial way.

Q3)[Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 3 [Receptor agonist (activating compound)]

Q1)[Clarity: No] The claim lacks clarity, since the agonist is a compound specified by its function or property, and we cannot say that the person skilled in the art can easily formulate a specific compound from its function or property, even upon consideration of common general technical knowledge.

[Enablement: No] The claim lacks enablement, since the application does not disclose a specific use of the compound, and the person skilled in the art cannot know "how to use" it.

Furthermore, the claim also lacks enablement because, other than the compounds obtained in the working examples, there is no disclosure of specific chemical structures, or any other matter which would serve as a clue to obtain such a compound. Therefore, it would require the person skilled in the art to perform undue experimentation to obtain such a compound, having a basic structure other than the structures of the compounds obtained in the working examples.

Q2)[Industrial Applicability: No] The claim also lacks industrial applicability, since the application does not disclose how to apply the receptor agonist (activating compound) in an industrial way.

Q3)[Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 4 [Pharmaceutical composition comprising receptor agonist (activating compound)]

Q1)[Clarity: No] The claim lacks clarity, because when the receptor agonist (activating compound) is unclear, a pharmaceutical composition comprising such agonist (activating compound) would also become unclear.

[Enablement: No] The claim also lacks enablement, because the person skilled in the art cannot understand how to obtain a specific agonist (activating compound) other than the compounds obtained in the working examples, and what sort of disease-treating composition the compound should be used to manufacture, even upon consideration of general common technical knowledge. It would require undue experimentation to perform such an invention.

Q2)[Industrial Applicability: No] In this case, the claim lacks industrial applicability as well.

Q3) [Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 5 [Pharmaceutical composition comprising specific compounds]

Q1) [Clarity: No] Since the specific function (e.g., its relationship to a specific disease) of the receptor is not disclosed, the claim referring to a "disease treatable by the agonist" of the said receptor is unclear.

[Enablement: No] The person skilled in the art cannot understand what sort of disease-treating composition the compound should be used in manufacturing, even upon consideration of general common technical knowledge.

Q2) [Industrial Applicability: No] In this case, the claim also lacks industrial applicability.

Claim 6 [Anti-receptor monoclonal antibody]

Q1) [Clarity: Yes] The claimed monoclonal antibody is specified by the antigen it recognizes. This is a common way to specify a subject matter in this technical field. Therefore, if the antigen is clear, a monoclonal antibody specified by the antigen is also considered clear.

[Enablement: No] Since the person skilled in the art cannot understand how to use the receptor, he/she also cannot understand how to use a monoclonal antibody recognizing the receptor, and thus, the claim lacks enablement .

Q2) [Industrial Applicability: No] Since the claim for the receptor lacks industrial applicability, a monoclonal antibody recognizing the receptor also lacks industrial applicability.

Case 4

Claim 1 [Receptor protein]

Q1) [Clarity: Yes] The receptor is specified by its amino acid sequence, and therefore is clear.

[Enablement: Yes] The relationship between the claimed receptor and a specific biological function or disease is disclosed in the application, and a screening method for obtaining anti-obesity compounds is also described and supported. The receptor is also actually produced. Therefore, the person skilled in the art could understand how to make and use the receptor. Thus, the claim meets enablement.

Q2) [Industrial Applicability: Yes] In this case, the claim meets industrial applicability.

Claim 2 [Screening method]

Q1) [Clarity: Yes] The claim meets clarity, since it is clear to the person skilled in the art, based on the working example described in the application, whatever conceivable changes in the experimental system would be available as the criteria of judgement, in choosing a receptor agonist (activating compound).

[Enablement: Yes] The person skilled in the art can understand, based on the working example described in the application, whatever conceivable changes in the experimental system would be available as the criteria of judgement, in choosing a receptor agonist (activating compound).

Furthermore, since the relationship between the claimed receptor and a specific disease is disclosed, the person skilled in the art can easily understand "how to use" the screening method utilizing said receptor. Therefore, the claim meets enablement.

Q2) [Industrial Applicability: Yes] In this case, the claim also meets industrial applicability, since it is clear from the specification how to apply the receptor in an industrial way.

Claim 3 [Receptor agonist (activating compound)]

Q1) [Clarity: No] The claim lacks clarity, since the agonist is a compound specified by its function or property, and we cannot say that the person skilled in the art can easily formulate a specific compound from its function or property, even upon consideration of common general technical knowledge.

[Enablement: No] The claim also lacks enablement because, other than the compounds obtained in the working examples, there is no disclosure of specific chemical structures, or any other matter which would serve as a clue to obtain such a compound. Therefore, it would require the person skilled in the art to perform undue experimentation to obtain such a compound, having a basic structure other than the structures of the compounds obtained in the working examples.

Q2) [Industrial Applicability: Yes] The claim meets industrial applicability, since if there would be such an agonist (activating compound), it would be useful for the manufacture of a novel anti-obesity drug.

Q3) [Other Comments] 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 this Case.

Claim 4 [Pharmaceutical composition comprising receptor agonist (activating compound)]

Q1) [Clarity: No] The claim lacks clarity, because when the receptor agonist (activating compound) is unclear, a pharmaceutical composition comprising such agonist (activating compound) would also become unclear.

[Enablement: No] The claim also lacks enablement, because the person skilled in the art cannot understand how to obtain a specific agonist (activating compound) other than the compounds obtained in the working examples, even upon consideration of general common technical knowledge. It would require undue experimentation to perform such an invention.

Q2) [Industrial Applicability: Yes] The application discloses that the composition can be used as an anti-obesity drug, and therefore is industrially applicable.

Q3) [Other Comments] See discussion in claim 3.

Claim 5 [Pharmaceutical composition comprising specific compounds]

Q1) [Clarity: Yes] A composition comprising specific compounds obtained from working examples is clear.

[Enablement: Yes] The person skilled in the art can understand what sort of disease-treating composition the compound should be used to manufacture, and furthermore, the effect of the compounds are supported by pharmacological data.

Q2) [Industrial Applicability: Yes] The application discloses that the composition can be used as an anti-obesity drug, and therefore is industrially applicable.

Claim 6 [Anti-receptor monoclonal antibody]

Q1) [Clarity: Yes] The claimed monoclonal antibody is specified by the antigen it recognizes. This is a common way to specify a subject matter in this technical field. Therefore, if the antigen is clear, a monoclonal antibody specified by the antigen is also considered clear.

[Enablement: Yes] If an antigen protein is obtainable, a monoclonal antibody that simply recognizes the antigen is also considered obtainable, using conventional methods. And if the person skilled in the art can understand how to make and use the receptor, he/she can also understand how to use a monoclonal antibody recognizing the receptor. In this case, both requirements are met, and thus, the claim meets enablement.

Q2) [Industrial Applicability: Yes] In this case, the claim also meets industrial applicability.