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Revision of Examination Guidelines for “Requirements for Description and Claims”

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Examination Guidelines for “Requirements for Description and Claims” such as support by the description [Art.36(6)(i),Patent Law], clarity [Art.36(6)(ii),Patent Law] and enablement [Art.36(4)(i),Patent Law] have been recently revised and have already been applied to the examination since October 1, 2011.

This revision aims to:

- (i) supplement and clarify the insufficient explanations, in order to prevent overly strict determinations and correct variations among the examiner’s determinations, and
- (ii) improve the consistency among the examination guidelines for each of the description requirements, as they have been revised at different times and therefore are inconsistent.

We would like to show some major points worth noting in this revision as follows.

1. Support by the description [Art.36(6)(i) ,Patent Law]

(1) This requirement is intended to prevent a patent protection for an invention which is not disclosed to the public.

As one of basic rules, this requirement is examined by looking into whether or not the claimed invention exceeds the scope stated in the detailed explanation of the invention in such a way that a person skilled in the art could recognize that a problem to be solved by the invention would be actually solved.

(2) The Examination Guidelines recite four typical types violating this requirement. Among them, we often encounter the third type violation, that is, the content disclosed in

the detailed explanation of the invention can neither be expanded nor generalized to the scope of the claimed invention even in light of the common general knowledge as of the filing.

To this third type violation, revised Examination Guidelines clearly state that this type should not be applied independently of the problem to be solved by the invention. It may help avoid too restrictive position of an examiner on the scope of claims by the specific examples stated in the detailed explanation of the invention.

(3) Against the third type violation, the applicant may, in a written opinion, point out the common general knowledge other than that taken into account by the examiner when making such determination, and argue that in light of such common general knowledge, the content disclosed in the detailed explanation of the invention can be expanded or generalized to the scope of the claimed invention.

Moreover, the applicant may also submit a certificate of experimental results to support such argument presented in the written opinion.

Case example 6 in the revised Examination Guidelines can be exemplified for such successful response of the applicant (please refer to [Appendix 1](#)), while case example 4 in the revised Examination Guidelines is rather a negative example in this respect (please refer to [Appendix 2](#)).

2. Clarity [Art.36(6)(ii),Patent Law]

(1) Revised Examination Guidelines provide clearer definition of “clarity” or “the clear scope of the claimed invention” in such a way that it is possible to understand whether a specific product or process falls within the scope of the claimed invention.

(2) Moreover, revised Examination Guidelines state that an application does not constitute this type of violation merely because the technical meaning of a matter to define the invention cannot be understood.

In order to reject the application as lack of clarity from the view point of the technical meaning of a matter, it is necessary not only that the technical meaning of a matter to define the invention cannot be understood, but also it is not evident that the matters to define the invention are deficient in light of the common general knowledge as of the filing.

3. Enablement [Art.36(4)(i),Patent Law]

(1) According to the Examination Guidelines, if a person skilled in the art cannot understand how to carry out the invention on the basis of teachings in the statements of the

description and drawings, as well as the common general knowledge as of the filing, then, such a detailed explanation of the invention should be deemed insufficient for enabling such a person to carry out the invention. For example, if a person skilled in the art who intends to work the invention would have to make trials and errors, beyond the reasonably-expected extent, such a detailed explanation of the invention should not be deemed sufficient.

(2) In relation to this requirement, we would like to introduce the case examples 8 and 10 in the revised Examination Guidelines.

Both case examples relate to a medicinal product invention. Case example 8 represents an ordinary case in that enablement requirement is not met without a pharmacological test (please refer to [Appendix 3](#)), while case example 10 represents an exceptional case in that enablement requirement (and support by the description) is met without a pharmacological test (please refer to [Appendix 4](#)).

4. Our Comments

Under the current Japanese patent practice in the filed of chemistry or biology, especially in relation to new chemical compound or medicinal product, it is considered to be indispensable that the patent specification as filed include experimental results which substantiate the technical effect such as pharmacological effect.

Moreover, substantial reason is stringently required for expanding or generalizing such experimental results to the scope of the claimed invention.

Thus, we would like to recommend the followings to obtain a patent right having broader scope and more strengthened validity.

(i) Theoretical rationale such as appropriate common general knowledge be presented that can substantiate the expansion or generalization of the experimental results in the patent specification as filed to the scope of the claimed invention.

You may present such theoretical rationale in a written response to an official notice of refusal. However, it is much preferable that such theoretical rationale is included in the patent specification as filed.

(ii) In case that there are no such theoretical rationales, sufficient number of experimental results in the patent specification as filed be presented that can support the entire scope of the claimed invention.

References

(1) Revision of Examination Guidelines for “Requirements for Description and Claims”

October 7, 2011, Japan Patent Office

http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/description_claims_rev.htm

(2) Revised Examination Guidelines for Description and Claims”

PDF file can be retrieved on the same website as shown in (1).

(3) Revision of relevant parts to “Requirements for Description and Claims”

PDF file can be retrieved on the same website as shown in (1).

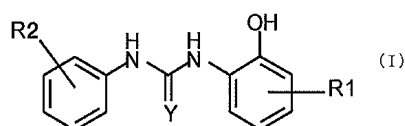
Best regards,
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Case 4**Scope of claims****[Claim 1]**

An anti-allergic drug containing a compound having enzyme A inhibitory activity as an active ingredient.

[Claim 2]

An anti-allergic drug of Claim 1, in which the compound having enzyme A inhibitory activity is represented by Formula (I):



wherein Y is either an oxygen atom or sulfur atom, and R₁ and R₂ are independently selected from the group consisting of hydrogen, halogen, nitro, cyano, and C1-6 alkyl.

Outline of the detailed explanation of the invention

The present invention relates to a new use of a compound having enzyme A inhibitory activity. A considerable number of compounds are known as those having enzyme A inhibitory activity, including compounds having various chemical structures such as those represented by General Formula (I) in Patent Gazette No. ○, and those disclosed generally or specifically in JP XX-XXXXXX A and Cited Reference △. Among those already known, compound A and compound B are preferable.

Examples show the pharmacological test method and result by which the anti-allergic action is confirmed in several specific compounds represented by Formula (I) (including compound A and compound B).

(However, there is no theoretical explanation that compounds having enzyme A inhibitory activity have an anti-allergic action.)

Outline of the reasons for refusal

- Article 36(6)(i), Article 36(4)(i) (Enablement Requirement): Claim 1

Claim 1 comprehensively describes an anti-allergic drug containing a compound defined by its property, "enzyme A inhibitory activity," as an active ingredient. However, the detailed explanation of the invention only states that it has been confirmed that the specific compound as defined in Claim 2 is useful as an active ingredient of an anti-allergic drug, and it does not show any theoretical or experimental grounds to prove the usefulness as an anti-allergic drug of any compound in general having enzyme A inhibitory activity. Furthermore, the scope of an active ingredient defined only by its property may include compounds having various chemical structures, but it is common general knowledge as of the filing that compounds whose chemical structures significantly differ from each other do not necessarily have the same pharmacological action. No ground can be found for expanding or generalizing the content disclosed in the detailed explanation of the invention, to the scope of the invention of Claim 1, which also covers an anti-allergic drug containing, as an active ingredient, a compound whose chemical structure significantly differs from that of the compound defined in Claim 2.

Thus, the invention of Claim 1 exceeds the scope stated in the detailed explanation of the invention.

Furthermore, in light of the statement of the detailed explanation of the invention, as well as the common general knowledge as of the filing, which are mentioned above, the statement of the detailed explanation of the invention cannot be deemed to be informative enough to use an anti-allergic drug containing any compound in general having enzyme A

inhibitory activity as an active ingredient.

Thus, the detailed explanation of the invention is not stated clearly or sufficiently as to enable a person skilled in the art to work the invention of Claim 1.

Notes

Claim 1 describes the invention of an anti-allergic drug containing a compound defined by its property, "enzyme A inhibitory activity," as an active ingredient. As it is easy to understand the compound having said property in light of the common general knowledge as of the filing, such compound as defined by the property, "enzyme A inhibitory activity," is sufficiently specified from a technical perspective, and the invention can be clearly identified from the statement of Claim 1. Thus, Claim 1 satisfies the requirement of Article 36(6)(ii).

Claim 2 satisfies both the requirements of Article 36(6)(i) and (ii), and the detailed explanation of the invention satisfies the enablement requirement with regard to Claim 2.

Applicant's response

The applicant can overcome all of the reasons for refusal by deleting Claim 1 and maintaining only Claim 2.

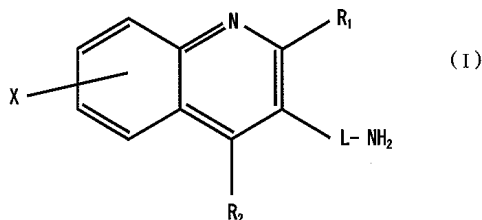
(Supplementary explanation)

The scope of an active ingredient defined only by its property may include compounds having various chemical structures. The detailed explanation of the invention only shows examples wherein an anti-allergic action is confirmed in several compounds represented by Formula (I), but it does not indicate any theoretical or experimental grounds to prove the usefulness as an anti-allergic drug of any compound in general having enzyme A inhibitory activity. Because of this, it is difficult for the applicant to indicate any information as proof of satisfying the requirement of Article 36(6)(i) and the enablement requirement (e.g. the common general knowledge as of the filing other than that taken into consideration by the examiner when making determination).

In such case, the reasons for refusal cannot be overcome even when the applicant submits a certificate of experimental results after the filing to make up for the deficiency of the matters stated in the detailed explanation of the invention, thereby arguing that, in light of the common general knowledge as of the filing, the content disclosed in the detailed explanation of the invention can be expanded or generalized to the scope of the claimed invention, and that the detailed explanation of the invention is stated clearly and sufficiently as to enable a person skilled in the art to work the invention of Claim 1.

Case 6**Scope of claim****[Claim 1]**

A peptidase Z inhibiting agent containing a compound represented by Formula (I) or salts thereof as an active ingredient:



wherein R_1 and R_2 are a hydrocarbon group with 3 to 10 carbon atoms, X is a halogen group, and L is an alkylene group with 1 to 10 carbon atoms.

Outline of the detailed explanation of the invention

Although compounds represented by Formula (I) or salts thereof are publicly known compounds, it has been unknown that they have peptidase Z inhibitory activity.

The present invention relates to the finding that the compounds represented by Formula (I) or the salts thereof have peptidase Z inhibitory activity.

Examples show formulations of a peptidase Z inhibiting agent using several compounds represented by Formula (I), and indicate the pharmacological test method and results by which peptidase Z inhibitory activity is confirmed with regard to the compound wherein both R_1 and R_2 are propyl groups, L is a butylene group, and X is chlorine group.

Outline of the reasons for refusal

- Article 36(6)(i), Article 36(4)(i) (Enablement Requirement)

Claim 1 comprehensively describes a peptidase Z inhibiting agent containing a compound represented by Formula (I) as an active ingredient, whereas the detailed explanation of the invention only states that peptidase Z inhibitory activity has been confirmed with regard to a specific compound wherein both R_1 and R_2 are propyl groups. The scope of compounds represented by Formula (I) include compounds with a large side chain, such as those wherein both R_1 and R_2 are naphthyl groups. However, it is common general knowledge as of the filing that the difference in the size of a side chain would, due to three-dimensional interference, change the interaction with a specific enzyme. No ground can be found for expanding or generalizing the content disclosed in the detailed explanation of the invention to the scope of the invention of Claim 1, which also covers a peptidase Z inhibiting agent containing, as an active ingredient, a compound which significantly differs from said specific compound in terms of the size of a side chain.

Thus, the invention of Claim 1 exceeds the scope stated in the detailed explanation of the invention.

Furthermore, in light of the statement of the detailed explanation of the invention, as well as the common general knowledge as of the filing, which are mentioned above, the statement of the detailed explanation of the invention cannot be deemed to be informative enough to use a peptidase Z inhibiting agent containing any compound in general represented by Formula (I) as an active ingredient.

Thus, the detailed explanation of the invention is not stated clearly or sufficiently as to enable a person skilled in the art to work the invention of Claim 1.

Applicant's response

The applicant can overcome all of the reasons for refusal by submitting a written opinion in which he/she points out the common general knowledge as of the filing, other than that taken into consideration by the examiner when making determination, to the effect that compounds having the same bone structure tend to have the same activity despite some difference in the size of a side chain, and argues that in light of the entire statement of the detailed explanation of the invention, as well as such other common general knowledge, the content disclosed in the detailed explanation of the invention can be expanded or generalized to the scope of the invention of Claim 1. He/she should also argue that the detailed explanation of the invention is stated clearly and sufficiently as to enable a person skilled in the art to work the invention of Claim 1. In order to support such argument presented in the written opinion, the applicant should also submit a certificate of experimental results which shows, for example, that among the compounds represented by Formula (I) used in the formulations, several compounds with a large side chain (e.g. naphthyl group) actually have peptidase Z inhibitory activity.

(Supplementary explanation)

The reasons for refusal may not be overcome if both the matter of common general knowledge that the examiner has taken into consideration when making determination and the matter of common general knowledge that the applicant points out in his/her written opinion existed at the time of the filing, and which of these matters of common general knowledge is appropriate for the invention of Claim 1 cannot be determined based on the applicant's argument alone (which means that the truth or falsity of the applicant's argument is unclear) (refer to 2.2.1.4(3) and 3.2.3(2)). In such case, if the applicant, by submitting a certificate of experimental results, successfully proves that the matter that the applicant argues in his/her written opinion is appropriate as common general knowledge for the invention of Claim 1, it is established that the content disclosed in the detailed explanation of the invention can be expanded or generalized to the scope of the invention of Claim 1, and that the detailed explanation of the invention is stated clearly and sufficiently as to enable a person skilled in the art to work the invention of Claim 1. In consequence, the reasons for refusal can be overcome.

Case 8**Scope of claim****[Claim 1]**

An antiemetic drug containing ingredient A as an active ingredient.

Outline of the detailed explanation of the invention

The present invention relates to a new use of ingredient A (this substance itself is publicly known).

The detailed explanation of the invention states the effective dose of ingredient A, the mode of administration, and the method of formulation.

(However, it does not contain any statement of the pharmacological test method or results. Furthermore, the use of ingredient A in an antiemetic drug cannot be presumed from the common general knowledge as of the filing.)

Outline of the reasons for refusal

- Article 36(4)(i) (Enablement Requirement), Article 36(6)(i)

The detailed explanation of the invention does not contain any statement of the pharmacological test method or results which show the use of ingredient A as an antiemetic drug. Furthermore, as the use of ingredient A in an antiemetic drug cannot be presumed from the common general knowledge as of the filing, the statement of the detailed explanation of the invention cannot be deemed to be informative enough to use an antiemetic drug containing ingredient A as an active ingredient.

Thus, the detailed explanation of the invention is not stated clearly or sufficiently as to enable a person skilled in the art to work the invention of Claim 1, which relates to an antiemetic drug containing ingredient A as an active ingredient.

In addition, Claim 1 describes an invention relating to an antiemetic drug containing ingredient A as an active ingredient, whereas the detailed explanation of the invention, in light of the statement of the detailed explanation of the invention, as well as the common general knowledge as of the filing, which are mentioned above, cannot be regarded as disclosing the invention in such a way that a person skilled in the art could recognize that the problem to be solved by the invention of Claim 1, which is providing an antiemetic drug containing ingredient A as an active ingredient, would be actually solved.

Thus, the invention of Claim 1 is not stated in the detailed explanation of the invention.

Applicant's response

The reasons for refusal cannot be overcome even when the applicant argues that ingredient A functions as an antiemetic drug by submitting a certificate of experimental results which shows the pharmacological test method and results.

(Supplementary explanation)

The description initially attached to the application does not contain any statement of the pharmacological test method or results which show the use of ingredient A as an antiemetic drug. Furthermore, the use of ingredient A in an antiemetic drug cannot be presumed from the common general knowledge as of the filing. Therefore, the reasons for refusal cannot be overcome even when the applicant argues that the detailed explanation of the invention is stated clearly and sufficiently as to enable a person skilled in the art to work the invention of Claim 1, and that the invention of Claim 1 is stated in the detailed explanation of the invention on the basis of only a certificate of experimental results which is submitted after the filing.

(See: Tokyo High Court Decision dated October 30, 1998 (Hei 8 (Gyo-Ke), No.201, a case to seek rescission of the JPO decision.)

Case 10

Scope of claim

[Claim 1]

An agent for preventing arteriosclerosis that contains substance X as an active ingredient.

Outline of the detailed explanation of the invention

The present invention relates to the finding that substance X has a strong hydroxy radical scavenging activity and it is extremely effective in preventing arteriosclerosis that is induced by active oxygen.

Example 1 shows the method of producing substance X, and Example 2 shows the experimental results by which it is confirmed that substance X has hydroxy radical scavenging activity. Example 3 specifically describes the method of preparing an agent for preventing arteriosclerosis which contains substance X as an active ingredient.

Outline of the reasons for refusal

No reason for refusal

Notes

The detailed explanation of the invention shows the experimental results by which it is confirmed that substance X has a high hydroxy radical scavenging activity. It is common general knowledge as of the filing that a substance having hydroxy radical scavenging activity is effective in preventing arteriosclerosis. Accordingly, even without any pharmacological test method or results which directly show that substance X is effective for the prevention of arteriosclerosis, the statement of the detailed explanation of the invention can be deemed to be informative enough to use an agent for preventing arteriosclerosis that contains substance X as an active ingredient.

Thus, the detailed explanation of the invention is stated clearly and sufficiently as to enable a person skilled in the art to work the invention of Claim 1, which relates to an agent for preventing arteriosclerosis that contains substance X as an active ingredient, and the detailed explanation of the invention satisfies the enablement requirement with regard to Claim 1.

In addition, in light of the statement of the detailed explanation of the invention, as well as the common general knowledge as of the filing, which are mentioned above, the detailed explanation of the invention can be regarded as disclosing the invention in such a way that a person skilled in the art could recognize that the problem to be solved by the invention of Claim 1, which is providing an agent for preventing arteriosclerosis that contains substance X, would be actually solved.

Thus, the invention of Claim 1 is stated in the detailed explanation of the invention, and Claim 1 satisfies the requirement of Article 36(6)(i).