Trilateral Comparison of Description Requirements in Notices of Reasons for Refusal
-Comparison of Tendencies in Reasons for Refusal among the Trilateral Offices-

The Second Subcommittee
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Abstract: In fiscal 2007, the First Patent Committee began verifying the rationality of the criteria for description requirements in Japan by comparing actual applications filed in Japan and those in foreign countries, and identifying points of note for description requirements at the time of filing applications. Sampled cases yielding different results among the trilateral families were examined for international differences in judgment (in Japan, US, Europe, China, and Korea) on the basis of Japanese court decisions and appeal/trial decisions in fiscal 2007, US court decisions and examinations in fiscal 2008, and European appeal/trial decisions in fiscal 2009. When the US was the base country, there was no bias of one-sided strictness, although some differences were found among individual cases. This appeared to conflict with the user's conception, and was attributed to the fact that the conclusion was reached only for cases in which an appeal/trial or lawsuit was made in either Japan, the US, or Europe. Hence, we explored in detail the reasons for refusal to actual applications filed to the trilateral authorities, and analyzed the tendencies in the reasons for refusal of description requirements among the Trilateral Patent Offices. The findings are reported below.

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1. Introduction

With regard to description requirements for the statement of the Description, etc., in patent application [description requirements for the Scope of Claims (① support requirements for inventions, ② clarity requirements for in-

ventions) and description requirements for the Description (③ enablement requirements)], any violation alone constitutes a reason for refusal (Patent Act Article 49) or a ground for invalidation (Patent Act Article 123), and can also be a reason for an argument of invalidity. Description requirements can be deemed an important requisite not only for disclosing an invention to acquire a patent right, but also for exercising the patent right.

In recent years, the Trilateral Patent Offices (the Japan Patent Office, the United States Patent and Trademark Office, and the European Patent Office) have conducted a series of comparative studies concerning the actual practice of patent examination so as to facilitate the generation of application documents of high quality. In December 2007, the results of a comparative study of legal situations and examination standards at the Trilateral Patent Offices were published. In June 2008, the results of a case study on description requirements[1] were published. In these surveys, it was found that although the legal situations and examination standards of the Trilateral Patent Offices were similar, the manners of their application to specific cases differed.

On the other hand, in our mid- to long-term action scheme for fiscal 2007-2009, we compared the judgments of description requirements at the Trilateral Patent Offices on the basis of actual court decisions and appeal/trial decisions. However, the results did not reflect the judgments made in actual examinations because those investigations were based on court decisions and the like.

Hence, we proceeded to compare judgments concerning description requirements at the Trilateral Patent Offices on the basis of actual cases of examination.

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2. Objective and Background for Fiscal 2012

As stated above, between fiscal 2007 and fiscal 2009, the First Patent Committee analyzed sampled cases of lawsuits and appeals/trials for differences in judgments of description requirements between Japan and foreign countries. The results revealed no major differences in the strictness of examination between Japan and the US or Europe.[2-4] However, because the survey results from the Trilateral Patent Offices were obtained exclusively from cases involving lawsuits and the like, they do not always reflect the reality in the majority of cases that do not reach such processes.

Meanwhile, regarding description requirements, there have been a number of suggestions posing the question of whether stricter assessment is made in Japanese examinations than in European and US examinations.[1,5,6] In fact, practical affairs seem to be handled with stricter judgments of description requirements in Japan than in the US or Europe.

Against this background, we compared the judgments on description requirements in the reasons for refusal shown in examinations at the Trilateral Patent Offices by comparing actually issued notices of reasons for refusal.

3. Details of the Survey

A total of 1,013 PCT applications that were internationally published in the first week of August 2006, and transferred to Japan, were sampled, of which 442 applications encountering first actions at all the Trilateral Patent Offices were examined as the analytical population. The first actions at the Trilateral Patent Offices were surveyed for ① overall tendencies in the number of violations of description requirements and ② tendencies in the number of such violations by technical field.

Also examined were ③ tendencies in the judgments concerning description requirements by checking in detail the first actions at the Trilateral Patent Offices.

Here, the first actions included not only what are called "first notices of reasons for refusal," but also judgments on description requirements shown in European search reports and the like. We examined first actions to compare matters pointed out because we thought that all violations of description requirements arising from the original Description, etc., should be pointed out in the first action stage (at least the first notice of reasons for refusal). In addition, we investigated international publications as of the first week of August 2006 for the reason of sampling cases about five years after the elapse of entry in the national phase, taking into account the timing of the ini-

tiation of examination in Europe.

The survey results are described in sequence below. Regarding the results of the aforementioned survey ③, actual cases are described with a focus on the field of pharmaceuticals and chemicals, in which characteristic differences were found in the judgments of description requirements among the Trilateral Patent Offices.

4. Overall Tendencies in Notices of Reasons for Refusal

The above-described sampled cases were examined for the frequency of violations of each type of description requirements (support requirements, clarity requirements, and enablement requirements) pointed out in the first action stage. The overall tendencies shown in Table 1 were revealed.

Table 1. Tendencies in violations of description requirements pointed out at the Trilateral Patent Offices

	Number of violations pointed out (442 sampled cases)			
	Total	JP	US	EU
Support	120	79	27	34
Clarity	367	239	180	187
Enablement	109	75	49	19
Total for all description requirements	377	259	204	204

In the 442 cases sampled, the number of violations of description requirements pointed out in the first action stage was 259 for Japan, 204 for the US, and 204 for Europe.

Comparing the number of violations of description requirements pointed out among the Trilateral Patent Offices, the figure for Japan was found to be about 1.3 to 4 times higher than those for the US and Europe; statistically, the percentage ratio of violations of description requirements pointed out was highest in Japan.

A comparison by each type of description requirements revealed an overall tendency for violations of clarity requirements to be pointed out most frequently. Violations of clarity requirements accounted for 92% of all violations of any type of description requirements pointed out in Japan (239/259), 88% (180/204) in the US, and 92% (187/204) in Europe; the tendency was similar among the Trilateral Patent Offices. As for support requirements and enablement requirements, the percentage of violations was 31% (79/259) and 29% (75/259), respectively, in Japan; 13% (27/204) and 24% (49/204), respectively, in the US; and 17% (34/204) and 9% (19/204), respectively, in Europe. Thus the percentage of violations of support requirements tended to be higher in Japan than in the US and Europe. Therefore, it can be estimated that these two

types of description requirements have greater influence on patent examination in Japan than in the US and Europe.

5. Tendencies by Technical Field

5.1. Pharmaceuticals and Chemicals

Table 2. Tendencies in violations of description requirements pointed out in the field of pharmaceuticals and chemicals

	Number of violations pointed out (208 sampled cases in the field of pharmaceuticals and chemicals)			
	Total	JP	US	EU
Support	91	60	21	28
Clarity	188	127	100	88
Enablement	86	61	43	16
Total for all description requirements	195	142	123	101

In the field of pharmaceuticals and chemicals, violations of clarity requirements were the most frequently pointed out, in line with the overall tendencies; any violation of clarity requirements was pointed out at at least one of the Trilateral Patent Offices in 90% of the 208 cases sampled (188/208). Of the 188 cases of violations of clarity requirements pointed out at at least one of the Trilateral Patent Offices, the percentage of violations of clarity requirements was 68% (127/188) for Japan, 53% (100/188) for the US, and 47% (88/188) for Europe; thus, the percentage was slightly higher for Japan.

Any violation of support requirements was pointed out at at least one of the Trilateral Patent Offices in 44% of the 208 cases sampled (91/208). Of the 91 cases of any violation of support requirements pointed out at at least one of the Trilateral Patent Offices, violations of support requirements accounted for 66% (60/91) in Japan, 23% (21/91) in the US, and 31% (28/91) in Europe; Japan tended to have a higher percentage of violations of support requirements pointed out than the US and Europe, and no major difference was found between the US and Europe.

On the other hand, any violation of enablement requirements was pointed out at at least one of the Trilateral Patent Offices in 41% of the 208 cases sampled (86/208). Of the 86 cases of any violation of enablement requirements pointed out at at least one of the Trilateral Patent Offices, violations of enablement requirements accounted for 71% (61/86) in Japan, 50% (43/86) in the US, and 19% (16/86) in Europe; Japan and the US thus tended to have a higher percentage of violations of enablement requirements pointed out than Europe, and Japan also tended to have a higher percentage of violations of enablement requirements pointed out than the US.

In addition, Japan exhibited a characteristic tendency in that both violations of support requirements and those of enablement requirements were often concurrently pointed out (data not shown in Table 2).

The above-described results revealed the following tendencies as a whole in the field of pharmaceuticals and chemicals.

- In Japan, violations of support requirements and violations of enablement requirements were more likely to be pointed out than in the US and Europe.
- In the US, violations of clarity requirements were most likely to be pointed out, followed by violations of enablement requirements; enablement requirements were judged relatively rigorously.
- In Europe, violations of clarity requirements and violations of enablement requirements were less likely to be pointed out than in Japan and the US, with the percentage of violations of enablement requirements pointed out being particularly low.

5.2. Machinery and Electric Appliances

In the field of machinery and electric appliances, violations of clarity requirements were most frequently pointed out, in line with the overall tendencies.

Table 3. Tendencies in violations of description requirements pointed out in the field of machinery and electric appliances

	Number of violations pointed out (234 sampled cases in the field of machinery and electric appliances)			
	Total	JP	US	EP
Support	29	19	6	6
Clarity	179	112	80	99
Enablement	23	15	6	3
Total for all description requirements	182	117	81	103

Any violation of clarity requirements was pointed out at at least one of the Trilateral Patent Offices in 76% of the 234 cases sampled (179/234). The percentage of violations of clarity requirements out of the 179 cases in which any violation of clarity requirements was pointed out at at least one of the Trilateral Patent Offices was 63% (112/179) for Japan, 45% (80/179) for the US, and 55% (99/179) for Europe; the percentage was higher for Japan.

In the field of machinery and electric appliances, the percentage of violations of support requirements or violations of enablement requirements pointed out among the 234 cases sampled was about 1-10%, which was lower than in the field of pharmaceuticals and chemicals. In ad-

dition, no major difference was found in the judgment of violations of support requirements and violations of enablement requirements pointed out among the Trilateral Patent Offices.

In summary, in the field of machinery and electric appliances, violations of clarity requirements were frequently pointed out, but the percentage of violations of other types of description requirements was lower at all the Trilateral Patent Offices; as a whole, violations of description requirements tended to be unlikely to be pointed out.

The above-described results revealed the following tendencies as a whole in the field of machinery and electric appliances.

- In Japan, violations were more likely to be pointed out for all types of description requirements than in the US and Europe, although the differences were not so large. Violations of support requirements and violations of enablement requirements were pointed out at moderate percentages of about 6-8% of the 234 cases sampled.
- In the US and Europe, violations of support requirements and violations of enablement requirements were pointed out at extremely low percentages of less than 3% of the 234 cases sampled; violations of clarity requirements accounted for the majority of violations of description requirements.

5.3. Synopsis

The above-described statistical findings lead to the tendencies shown below.

First, it can be said that Japan has the highest rates of violations of description requirements being pointed out among the Trilateral Offices. This is true for both technical fields examined, and holds for all the three types of description requirements; therefore, this tendency is considered to be universal. It can therefore be concluded that violations of description requirements are most likely to be pointed out in Japan among the Trilateral Patent Offices.

On the other hand, comparing the tendencies for violations of description requirements among the Trilateral Patent Offices by technical field, some biases are evident. First, for all of the three types of description requirements, the percentage of violations pointed out was higher in the field of pharmaceuticals and chemicals than in the field of machinery and electric appliances. This is generally true for the Trilateral Patent Offices, although there some variation exists. In terms of the percentage of violations of description requirements pointed out in Japan and the US, in particular, a considerable difference was found between the two technical fields.

Comparing the biases of the violations of each type of description requirements pointed out by technical field,

still more conspicuous tendencies are evident. A finding of note was that the percentage of violations of support requirements or violations of enablement requirements was outstandingly higher in the field of pharmaceuticals and chemicals than in the field of machinery and electric appliances. Specifically, the percentage of violations of support requirements pointed out at the Trilateral Patent Offices as a whole was 44% (91/208) in the field of pharmaceuticals and chemicals and 12% (29/234) in the field of machinery and electric appliances; the percentages in Japan alone were 29% (60/208) and 8% (19/234), respectively. The percentage of violations of enablement requirements pointed out at the Trilateral Patent Offices as a whole was 41% (86/208) in the field of pharmaceuticals and chemicals and 10% (23/234) in the field of machinery and electric appliances, while the percentages in Japan alone were 29% (61/208) and 6% (15/234), respectively.

In summary, Japan was found to have the highest percentage of violations of description requirements pointed out among the Trilateral Patent Offices. Comparisons by technical field revealed higher percentages of violations of description requirements pointed out in the field of pharmaceuticals and chemicals than in the field of machinery and electric appliances, with remarkably higher percentages of violations pointed out for support requirements and enablement requirements.

6. Case Reviews (Pharmaceuticals and Chemicals)

As far as the field of pharmaceuticals and chemicals is concerned, the above-described statistical analysis revealed characteristic tendencies in the judgment of violations of description requirements at the Trilateral Patent Offices. This finding is attributable to the possible greater reflection of differences in the viewpoints on the judgments of violations of description requirements among the Trilateral Patent Offices than in other technical fields because the experimental section and logical explanation play a major role in the understanding of the details of the invention.

Hence, we checked details of the violations of description requirements pointed out in the first action stage in the field of pharmaceuticals and chemicals at the Trilateral Patent Offices. Shown below are case narratives based on comparative results.

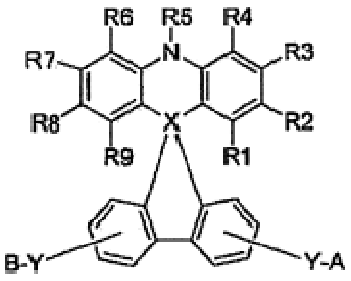
6.1. Enablement Requirements

① Case 1
(i) Bibliography
Title of the Invention:
NOVEL ORGANIC LIGHT EMITTING DEVICE MATERIAL AND LIGHT

EMITTING DEVICE USING THE SAME
Japanese patent application number (*ko-hyo* publication number):
JP Application 2007-529722 (JP-T-2008-511155)
International application number (international publication number):
PCT/KR2005/003169 (WO2006/080637)
US application number (US publication number):
US11/66085 (US2007/0292715)
European application number (European publication number):
EP05856354 (EP1791927)

(ii) Summary of the first reason(s) for refusal in Japan

The Examiner asserted that for the compound represented by [CHEMICAL FORMULA 1], described in claim 1, no embodiment is given in the Description or elsewhere (only seven structurally similar compounds described in Examples), and that it remains unknown to those skilled in the art whether other compounds are equivalently useful as organic light emitting devices, pointing out that the invention described in the claim in question does not fulfill the enablement requirements.



[CHEMICAL FORMULA 1]

(iii) Results of examinations concerning description requirements at the Trilateral Patent Offices

Japan: Violations of clarity requirements and enablement requirements.
US: Violation of clarity requirements.
Europe: Violations of support requirements and enablement requirements.

In the Japanese and European examinations, it was judged that enablement requirements were not fulfilled, with the compounds disclosed in the Examples as the starting point.

(iv) Discussion

In this case, an effect of the invention was verified for all of the seven compounds produced according to the Examples. Considering the fact that a site of electron assembly can serve as a key site for a light-emitting material, the judgment made in the Japanese examination that it remained unknown whether the invention is uniformly effective for all compounds other than those described in the Examples appears to be somewhat rigorous to the Applicant.

In the European examination as well,

it was pointed out that it remained unknown whether the invention is also applicable as a device to compounds other than those described in the Examples. Although this is also true for the Japanese examination, a more detailed judgment was made in the Japanese examination concerning the applicability of the invention to "other compounds" having a different functional group other than those in any of the compounds described in the Examples, taking note of the choice of functional group in the chemical formula of interest. In contrast, the European examination did not mention individual functional groups, but made a judgment on the possibility of enablement of compounds other than those described in the Examples.

Hence, the official approach to judging the fulfillment of enablement requirements in patent examination appears to be somewhat different between Japan and Europe.

In the US, violations of clarity requirements were pointed out; however, these suggestions did not significantly limit the scope of the compound described in claim 1.

② Case 2

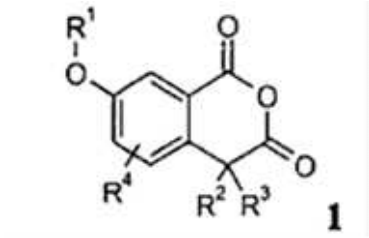
(i) Bibliography

Title of the Invention:
METHOD FOR PRODUCING ISOCHROMANE AND DERIVATIVES THEREOF

Japanese patent application number (*ko-hyo* publication number):
JP Application 2007-552629
(JP-T-2008-528545)
International application number (international publication number):
PCT/EP2006/050401 (WO2006/079622)
US application number (US publication number):
US11/275731 (US2006/0173196)
European application number (European publication number):
EP06707815 (EP1844033)

(ii) Summary of the first reason(s) for refusal in Japan

The Examiner asserted that for the reaction described in claim 1, the orientation and selectivity in the Friedel-Craft reaction vary depending on the electrophilicity and binding position of the group R^4, that the production examples given in the Examples are no more than examples, and that there are also some cases in which desired products are not obtained to a sufficient extent from some of the compounds of Formula 1 with a broad range of substituents by the method according to the invention of the present application (the underline drawn by the author; the same applies below), pointing out that the claim in question does not fulfill the enablement requirements.



(iii) Results of examinations concerning description requirements at the Trilateral Patent Offices

Japan: Violations of support requirements, enablement requirements, and clarity requirements.

US: Violation of clarity requirements.

Europe: No indications.

Only in the Japanese examination, the application was judged not to fulfill enablement requirements with the only manufacturing method disclosed in the Examples as the starting point.

(iv) Discussion

In the Japanese examination of this case, the Examiner pointed out a violation of enablement requirements for the claim in question, showing specifically the probability that when producing a compound with a substituent other than those described in the Examples, a side reaction can occur in the presence of a different substituent.

In any invention of a method for manufacturing a product in the art, it is not impossible to estimate reaction results as to whether the position and choice of substituent influences the reaction (whether the reaction proceeds equivalently) on the basis of Example 1 while taking into account the electronic and steric effects of the substituent on the reaction site. Therefore, it appears that it cannot always be concluded that the invention is not applicable to any compound other than the claimed compound merely for the reason that only Example 1 is available. In this regard, the judgment in the Japanese examination of this case appears to be somewhat rigorous.

③ Case 3

(i) Bibliography

Title of the Invention:
PHENYL METHANONE DERIVATIVES AND THEIR USE AS GLYCINE TRANSPORTER 1 INHIBITORS

Japanese patent application number (*kohyo* publication number):
JP Application 2007-552553
(JP-T-2008-528526)

International application number (international publication number):
PCT/EP2006/000361 (WO2006/079467)

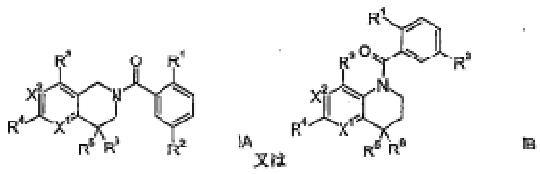
US application number (US publication number):
US11/338266 (US2006/0167023)

European application number (European publication number):
EP06706263 (EP1844045)

(ii) Summary of the first reason(s) for refusal in Japan

The Examiner asserted that because

the compounds represented by Formulas IA and IB described in claim 1 are understood to indicate a broad range of compounds, "it cannot be estimated that even compounds differing largely from the compounds disclosed in the Examples in terms of ring structure and substituent structure possess similar pharmacological activity, or can be produced in the same manner without requiring excess trials and errors," pointing out that the claim in question does not fulfill the enablement requirements.



(iii) Results of examinations concerning description requirements at the Trilateral Patent Offices

Japan: Violation of enablement requirements.

US: Violation of support requirements.

Europe: Violation of clarity requirements.

In the US and European examinations, the application was not rejected for the reason of a violation of enablement requirements, whereas only in the Japanese examination, it was judged that enable requirements were not fulfilled with the compounds disclosed in the Examples as the starting point. In contrast, in the US, a violation of support requirements was pointed out, with the assertion that the "cyclic amine, non-cyclic amine" (R^1) described in the claim in question is not described in the Description in a manner such that it can be understood as a structural feature as meant by the invention of this application. On the other hand, in Europe, no more than a violation of clarity requirements was pointed out, with the assertion that the descriptions of "lower alkyl" and the like are unclear.

(iv) Discussion

The invention of this application is characterized by its identity as "novel compounds having a common backbone" represented by the formulas IA and IB described in claim 1, and in the art, there are not a few cases in which the action and effect (pharmacological efficacy) vary as some substituents differ, even with the same common backbone.

However, it was only in Japan that a violation of enablement requirements was pointed out, and in this regard, the judgment concerning enablement requirements appears to be more rigorous in Japan than in the US and Europe.

Regarding the method of manufacturing the compounds, because "a specific manufacturing method" using "a known or available starting material" was disclosed, and because the manufacturing method is nothing more than "a common chemical reaction," it is unlikely that those skilled in the art would think,

merely for the reason that no Examples are available, that excess trials and errors are unavoidable to manufacture related compounds other than the compounds shown in the Examples (falling in the Scope of Claims).[7] In this regard, it appears that the judgment concerning the violation of enablement requirements in Japan in this case was somewhat rigorous.

④ Case 4

(i) Bibliography

Title of the Invention:
COMPOUNDS AND COMPOSITIONS AS PROTEIN KINASE INHIBITORS

Japanese patent application number (*kohyo* publication number):
JP Application 2007-553154 (JP-T-2008-528585)

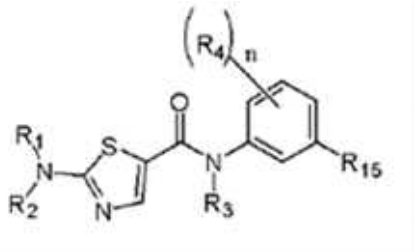
International application number (international publication number):
PCT/US2006/002266 (WO2006/081172)

US application number (US publication number):
US11/814912 (US2009/0105250)

European application number (European publication number):
EP06733803 (EP1841431)

(ii) Summary of the first reason(s) for refusal in Japan

Noting the substituent (R^{15}) of the compound pertaining to claim 1, the Examiner asserted that when the substituent is an atom other than the atoms shown in the Examples, electron density and backbone changes, and that even compounds having such a substituent cannot be recognized as being usable "in the same manner (as pharmaceutical compounds) as with the compounds specifically disclosed in the Description as pharmaceutical compounds with the same pharmacological activity."



(iii) Results of examinations concerning description requirements at the Trilateral Patent Offices

Japan: Violations of support requirements and enablement requirements.
US: Violation of enablement requirements.
Europe: No indications.

In the Japanese and US examinations, the application was judged to involve a violation of enablement requirements.

(iv) Discussion

In the Japanese examination of this case, in view of the fact that the primary backbone being an essential feature of the invention was shared, and that the indication concerned the substituent moiety (linkage moiety for the compound as a whole), which is not the pri-

mary backbone being an essential feature of the invention, it appears that the judgment that compounds not specified in the Examples were uniformly judged as not fulfilling enablement requirements was somewhat rigorous to the Applicant, solely for the reason that there were no Examples of compounds other than those with a carbon atom as a substituent.

In this case, for the sake of protecting the technical idea pertaining to the invention, we think that enablement requirements should be less rigorously judged (than in the current situation), taking into account the availability of more than one specific example given for novel pharmacologically active compounds with a common backbone.

The US examination was made from the viewpoints of "whether the compound can occur (can be produced)" and "whether it possesses the same pharmacological activity"; this was also true for the Japanese examination.

However, in the US examination, the functional group of the compound described in claim 1 was not questioned, but a violation of enablement requirements was pointed out for the reason that it remains unknown whether the compound "forms a hydrate or salvation product" and whether such a compound exhibits "the same pharmacological activity." Hence, the US judgment differed from Japan's in that the US examination was made with a focus not on the structure of the compound, but on the nature of the compound (whether it forms a hydrate or salvation product) and the form in which the compound exhibits its pharmacological activity (whether soluble in an aqueous medium and stable). This is a feature of the US examination, and there are some cases in which violations of enablement requirements are pointed out for the same reason (e.g., International Application No. PCT/IB2006/050285).

6.2. Support Requirements

① Case 5
(i) Bibliography
Title of the Invention:
METHOD FOR PRODUCING OPTICALLY ACTIVE HYDROXYMETHYLATED COMPOUNDS AND CATALYSTS USED THEREFOR
Japanese patent application number (*kohyo* publication number):
JP Application 2007-500589 (Domestic Republication 2006-080425)
International application number (international publication number):
PCT/JP2006/301293 (WO2006/080425)
US application number (US publication number):
US11/795525 (US2008/0139835)
European application number (European publication number):
EP06712459 (EP1852412)

(ii) Summary of the first reason(s) for refusal in Japan

The Examiner judged that "chiral bipyridine compounds" are described in claims 1 and 5, and that while a very broad range of compounds can be included in "chiral bipyridine compounds" according to the definitions given therein, these claims are in violation of support requirements because only some of such compounds are adequately supported in the Description.

In addition, with regard to claim 5, the Examiner judged that the claim is in violation of support requirements because "chiral bipyridine compounds" are applicable as catalysts only to some reactions, and because a broad range of other reactions are not adequately supported in the Description.

(iii) Results of examinations concerning description requirements at the Trilateral Patent Offices

Japan: Violations of support requirements and clarity requirements.

US: No indications.

Europe: No indications.

In the US and European examinations, there was no refusal for the reason of a violation of description requirements, whereas in the Japanese examination only, the judgment was made to determine whether support requirements were fulfilled on the basis of the compound disclosed in the Examples and the reaction using the compound as a catalyst. This examination result agrees with the above-described statistical data tendency in the field of pharmaceuticals and chemicals indicating that Japan is the most rigorous in judging violations of support requirements.

(iv) Discussion

The invention of this application comprises a method for producing optically active hydroxymethylated compounds (manufacturing method invention) as claimed in claim 1, and a catalyst (product invention) as claimed in claim 5. In the Description for the application, one specific example of "a chiral pyridine compound" was given, and the use of "a chiral pyridine compound" and the effect obtained were described to some extent.

In Japan, a violation of support requirements was pointed out not only for the product invention, but also for the manufacturing method invention for the reason that this case represents "a type (3) violation (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 common general knowledge as of the filing.)." In contrast, in the US and Europe, no judgment was made to the effect that description requirements were not fulfilled. Hence, it appears that the judgment of a violation

of support requirements in the Japanese examination of the present case is more rigorous than in the US and Europe.

② Case 6

(i) Bibliography

Title of the Invention:
METHOD AND COMPOSITION FOR TREATING CENTRAL NERVOUS SYSTEM DISORDERS

Japanese patent application number (*ko-hyo* publication number):
JP Application 2007-535160 (JP-T-2008-528440)

International application number (international publication number):
PCT/JP2006/301704 (WO2006/080549)

US application number (US publication number):
11/339495 (US2012/0225938)

European application number (European publication number):
11155203.0 (EP2332545)

(ii) Summary of the first reason(s) for refusal in Japan

The reasons for refusal pointed out in the examination in Japan include not only a novelty violation and an inventive step violation, but also an enablement requirement violation, a support requirement violation, and a clarity requirement. Regarding the support requirement violation, pointed out along with the enablement requirement, as a reason for refusal, it was pointed out that because the compounds specified in the Description constitute no more than a part of the compounds encompassed in the claims, and because no description is given about any action on any disease other than the disease described in the Examples, the inventions described in the claims are beyond the scope defined in the Description.

(iii) Results of examinations concerning description requirements at the Trilateral Patent Offices

Japan: Violations of support requirements, enablement requirements, and clarity requirements.

US: Violations of enablement requirements.

Europe: Violations of clarity requirements.

In Europe, reasons for refusal pertaining to description requirements pointed out included a violation of clarity requirements with the statement "the term '11-deoxy-prostaglandin compound' is unclear."

In the US, reasons for refusal pertaining to description requirements pointed out included a violation of enablement requirement with the statement "Although the invention is described as applicable to ischemia, Alzheimer's disease, and the like, the invention is not described as applicable to the treatment of all central nervous system diseases."

In the US and Europe, no reasons for

refusal were pointed out for the reason of a violation of support requirements.

(iv) Discussion

In this case, an invention relating to a compound for the treatment of a central nervous system disorder in mammalian subjects, including an effective amount of a 11-deoxy-prostaglandin compound was described in a claim. The structural formula of the 11-deoxy-prostaglanding compound was shown in claim 2 and thereafter, and a very large number of compounds were encompassed with the use of the Markush form.

On the other hand, in the Description, nothing more than the pharmacological data for up to three compounds and physical property data for 10 compounds were described.

In this case, in the Japanese examination, a violation of support requirements and a violation of enablement requirements were pointed out on the basis of there being too wide a range of statements in the claim compared with those in the Description. This case, as in case 5, can be said to represent "a type (3) violation (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 common general knowledge as of the filing.)."

On the other hand, in the US and European examinations, no violation of description requirements was pointed out based on too wide a range of the description of the claim, supporting the above-described statistical finding that support requirements are judged more rigorously in Japan than in the US and Europe.

③ Case 7

(i) Bibliography

Title of the Invention: INDOLOPYRIDINE, BENZOFURANOPYRIDINE, AND BENZOTHIENOPYRIDINE

Japanese patent application number (*kohyo* publication number):
JP Application 2007-552644 (JP-T-2008-528551)

International application number (international publication number):
PCT/EP2006/301293 (WO2006/079474)

US application number (US publication number):
US11/795762 (US2008/125452)

European application number (European publication number):
EP06724828.6 (EP1856117)

(ii) Summary of the first reason(s) for refusal in Japan

The Examiner pointed out violations of enablement requirements and support requirements because claims 13 through 20, which pertain to pharmaceuticals, are not described to allow a specific understanding of which compound possesses

what pharmacological action, and because their action is not obvious. In addition, the Examiner likewise pointed out violations of support requirements, as well as enablement requirements, for claims 14 through 20, which disclose techniques pertaining to diseases that are responsive to apoptosis induction, because there is no description to allow a specific understanding of the fact that the compound described in claim 1 possesses activity on apoptosis, and because such activity is not obvious.

(iii) Results of examinations concerning description requirements at the Trilateral Patent Offices

Japan: Violations of support requirements, enablement requirements, and clarity requirements.

US: Violations of enablement requirements.

Europe: No indications.

In the Japanese notice of reasons for refusal, for claim 13, which claims a pharmaceutical composition, a violation of support requirements, along with a violation of enablement requirements, was pointed out. (On the other hand, regarding clarity requirements, it was pointed out that "for example" was included in the claim, and that a trade name appeared in the claim.)

In the US, the Description described only pharmacological data for some compounds. It was judged that the application involved a violation of enablement requirements for the reason that although the claimed structural formula includes hundreds of compounds, the pharmacological efficacy of each cannot be predicted.

(iv) Discussion

The indications of violations of enablement requirements were basically the same between Japan and the US; however, in Japan, a violation of support requirements was also pointed out (this is the same in case 6 above). Regarding enablement requirements, the pharmacological effect can differ depending on the choice of substituent in the pharmaceutical field, and it can be thought reasonable that a violation of enablement requirements is pointed out for the reason that not all the compounds described in the claim exhibit similar action. However, a violation of support requirements was concurrently pointed out despite the fact that only a violation of enablement requirements should be pointed out; it appears that, in this regard, violations of support requirements are judged more rigorously in Japan than in the US and Europe.

6.3. Clarity Requirements

① Case 8

(i) Bibliography

Title of the Invention:

METHOD FOR COLOURING AN OPTICAL LENS COMPRISING A PRINTING PRIMER, AND OPTICAL COLOURED LENS COMPRISING SUCH A PRINTING PRIMER
Japanese patent application number (*ko-hyo* publication number):
JP Application 2007-551711 (JP-T-2008-528253)
International application number (international publication number):
PCT/FR2006/000167 (WO2006079715)
US application number (US publication number):
US11/814146 (US2008/0127432)
European application number (European publication number):
EP06709166.0 (EP1842087)

(ii) Summary of the first reason(s) for refusal in Japan

This case pertains to a method of colouring an optical lens comprising a particular transparent printing primer capable of being colored by ink jet printing, and another invention, and the clarity was questioned of the "water-dispersible polymer," "colloid," and "absorbent polymer" that constitute the Scope of Claims.

In the examination in Japan, the reason for refusal was pointed out because "the scope of substances encompassed in the 'water-dispersible polymer,' 'colloid,' and 'absorbent polymer' is unclear."

(iii) Results of examinations concerning description requirements at the Trilateral Patent Offices

Japan: Violations of clarity requirements and support requirements.
US: Claim objections.
Europe: No indications.

(iv) Discussion

In Europe, no reason for refusal due to an improper description was pointed out. In the US as well, a reason for refusal due to claim objections was pointed out, but it concerned nothing more than a formal deficiency concerning the usage of and/or.

In the Japanese examination, a violation of clarity requirements was pointed out merely for the reason that "the scope of substances encompassed in 'water-dispersible polymer,' 'colloid,' and 'absorbent polymer' was not clear," rather than the reason pertaining to the clarity of the terms.

Therefore, the assertion of being unclear can be attributed to the inability to clearly identify one invention from the description of one claim as a result of the unclearness of the scope of the substances encompassed.

It should be noted, however, that no adequate explanation appears to have been made with regard to why the description of the claim was judged as unclear when the scope of each substance is unclear. It is desired that the Examiner

specify in the notice of reasons for refusal the specific reason why the invention cannot be identified when the scope of substances encompassed is unclear (at least an explanation is desired that clarifies the violation type in the examination standards).

Such practice is expected to elucidate any discrepancy of recognition between the Examiner and the Applicant, ensuring that the Applicant will be afforded an opportunity to provide a full explanation through written arguments and the like.

② Case 9

(i) Bibliography

Title of the Invention:
ANTIBACTERIAL AGENTS
Japanese patent application number (*kohyo* publication number):
JP Application 2007-553156
(JP-T-2008-528586)
International application number (international publication number):
PCT/US2006/002280 (WO2006/081178)
US application number (US publication number):
US11/814612 (US2008/0146551)
European application number (European publication number):
EP20060719228 (EP1846416)

(ii) Summary of the first reason(s) for refusal in Japan

The Examiner asserted reasons for refusal not only because of a violation of clarity requirements, but also because of violations of industrial applicability, enablement requirements, and support requirements. Regarding the violation of clarity requirements, it was asserted that with regard to the substituent R_{13} in claim 1, it remains unknown which term is modified by the statement "contains up to four substituted or non-substituted hetero atoms in each ring, and at least one of rings (a) and (b) are aromatic rings," and that it is unclear whether R_{13} optionally contains a double ring or a carbon ring in addition to the heterocyclic ring system (A).

In addition to these reasons, a violation of enablement requirements and a violation of support requirements were pointed out.

(iii) Results of examinations concerning description requirements at the Trilateral Patent Offices

Japan: Violations of clarity requirements, enablement requirements, and support requirements.
US: No indications.
Europe: No indications.

In the US and Europe, unlike in Japan, no violations of clarity requirements were pointed out as reasons for refusal.

(iv) Discussion

A violation of clarity requirements was pointed out in the Japanese examination, whereas in the US and Europe, no viola-

tions of clarity requirements were pointed out for the same reason. Claim 1 might be judged as unclear due to a deficiency in the translation from English to Japanese.

6.4. Synopsis

Comparing the indications pointed out in the notices of reasons for refusal at the Trilateral Patent Offices, it appeared that the judgment is more rigorous in Japan than in the US and Europe with regard to violations of the three types of description requirements (especially violations of enablement requirements and violations of support requirements). Among the inventions in the field of pharmaceuticals and chemicals investigated herein, in particular, some cases were found in the Japanese examination in which description requirements were judged as being fulfilled for only the compounds described in the Examples and related compounds.

The results of the case investigations are described below for each of the three types of description requirements.

(1) Enablement requirements

Reviewing the individual cases, some cases were found in which the judgment appeared to be more rigorous in Japan than in the US and Europe.

The Japanese examination standards give examples of cases of a violation of enablement requirements pointed out, including "only the specific working mode is stated in the detailed explanation of the invention in a manner which enables a person skilled in the art to carry out the invention, and therefore, there is a well-founded reason that a person skilled in the art would be unable to carry out the parts of the claim which are not stated in the mode for carrying out the invention even by taking into account the statements of the description and drawings, as well as common general knowledge as of the filing. (Note that methods of experimentation and analysis may be among common general knowledge as of the filing.)" (cited from the Examination Guidelines for Patent and Utility Model in Japan). Examples of such well-founded reasons are given, including "A rational reasoning can be made that the strain-correction of the working example is inappropriate (3.2.2.2(1))" and "A rational reasoning can be made that such a process is inappropriate […] in view of technical matters such as a very large difference in the orientation (3.2.2.2(2))."

However, as in case 4, some cases were found in which the application was rejected for the reason of a violation of enablement requirements despite that fact that the indicated grounds (reasons) were abstract, such as changes in "electron density distribution" and "compound backbone." It is considered to be

somewhat rigorous to the Applicant who has published the essential nature of the invention (basic backbone, primary backbone) to make the uniform judgment that enablement requirements are not fulfilled for such a reason alone.

In addition, as mentioned in case 3, not a few cases were found in which it was judged that even when alternative substituents are mentioned for a compound described in a claim, enable requirements are not fulfilled for compounds not specified in the Examples. Other cases investigated included some cases in which a violation of enablement requirements was pointed out only in the Japanese examination for the reason that the Examples (particularly pharmacological data demonstrating action and effect) were only available for particular compounds (e.g., Japanese Patent Application 2007-551631 "NEW PHARMACEUTICAL COMPOSITION CONTAINING CANDESARTAN CILEXETIL AS LIPOPHILIC CRYSTALLINE SUBSTANCE").

There are not a few cases in which the nature of a pharmaceutical or chemical invention cannot be understood merely by knowing its structure; there are not a few cases in which the nature can be made to vary widely simply by changing some functional groups.[8,9] In these circumstances, in pharmaceutical and chemical inventions, a larger number of Examples are often required to fulfill enablement requirements for a broad range of invention.[10] However, it is usually impossible to provide Examples for all possible embodiments. Therefore, it appears that it can be judged that enablement requirements are fulfilled, provided that both more than one Example to support the characteristic part of the invention and a specific and logical explanation for rationalizing the same enablement for compounds other than those specified in the Examples are available.

(2) Support requirements

As stated for the above-described statistical findings, violations of support requirements tended to be often judged more rigorously in Japan than in the US and Europe.

For example, in case 5, despite an explanation based on a description in the Examples as the ground, it was judged that support requirements were not fulfilled in the Description except for some embodiments.

In case 6, it was judged that support requirements were not fulfilled for reasons that the compounds specified in the Description are nothing more than some of the compounds encompassed in the claim in question, and that no effect was described on diseases other than those described in the Examples.

In both cases, no violations of support requirements were pointed out in the US or Europe (this is also true for case 7).

In addition to these cases, more than one case was found in which no violations of support requirements were pointed out in the US and European examinations, whereas in Japan a violation of support requirements was pointed out. This finding demonstrates that in the field of pharmaceuticals, violations of support requirements were relatively rigorously judged in Japan.

In cases 6 and 7, both violations of support requirements and violations of enablement requirements were concurrently pointed out. Including these cases, many cases were found in which support requirements and violations of enablement requirements were concurrently pointed out in the field of pharmaceuticals and chemicals. This is a particularly commonly observed tendency in Japanese examinations.

Essentially, support requirements and enablement requirements are distinct from each other because they are evaluated using respective systems with different objectives.[11] Therefore, these types of description requirements should be separately evaluated and judged. In the chemistry field, however, there are not a few cases in which both violations of support requirements and violations of enablement requirements are concurrently pointed out without separately evaluating them in detail.

A recently published article[12] states that the judgment on a violation of support requirements and the judgment on a violation of enablement requirements sometimes agree with each other for use inventions, novel substance/composition inventions, and the like. The above-described tendencies in the chemistry field are considered to reflect these circumstances.

It should be noted, however, that in the context of lawsuits, actions that can be taken by the Applicant are considered to differ between violations of support requirements and violations of enablement requirements[13,14]; in some cases, it is too rigorous for the Applicant that violations of support requirements are easily pointed out even in cases that should essentially be judged as violations of enablement requirements. It is desired that more proper judgments be made in the examination process.

(3) Clarity requirements

Regarding clarity requirements in the field of pharmaceuticals and chemicals, it appeared overall that their violations were minor and could be dealt with by means of corrections and the like. Essentially, clarity requirements should be deemed fulfilled, provided that the description in the Scope of Claims is clear.[15] As long as adequate attention is exercised to this regard, it is considered possible to avoid violations of clarity requirements for pharmaceutical/chemical inventions.

(4) Points of note for preparing descriptions

With the above-described findings in mind, points of note for writing a good patent Description are discussed below.

First, the Applicant should endeavor to provide more than one Example with adequate variation for "any invention for which a patent right is most wanted," and to fully explain the invention described in the Scope of Claims to an extent that allows those skilled in the art to solve the problem, while accurately identifying the portion that is advantageous over the prior art (characterizing portion of the invention).

Meanwhile, for "any invention for which a patent right is wanted," the Applicant should endeavor to be able to explain that "the scope of the invention can be embodied in full" on the basis of the Examples in specific and logical manners, in addition to the aforementioned requirement for the Examples.

In addition, while attention should be exercised to describe the essential portion of the invention clearly and completely in preparing the Description, it is also necessary that the Applicant be careful not to deny the inventive step of his/her own invention due to excess awareness of the aforementioned specific and logical assertion.

7. Conclusion

We compared official judgments concerning description requirements at the Trilateral Patent Offices (Japan, the US, Europe) on the basis of actual cases, including notices of reasons for refusal. As a result, the number of indications pointed out with regard to description requirements tended to be higher in Japan than in the US and Europe. This agrees with the usual impression of actual practice and opinions given in published reviews.[1, 5, 6] On the other hand, a comparison of the tendencies for violations of each type of description requirements pointed out at the Trilateral Patent Offices revealed some cases in which more rigorous indications were pointed out in the US and Europe than in Japan, although this is not discussed in the text of this article. This is attributable to possible differences in the content of indications due to varied viewpoints of description requirements among the Trilateral Patent Offices. It can be concluded that a key to successful obtainment of a patent right at the Trilateral Patent Offices is for the Applicant to fully understand the varied regulations and their application among the Trilateral Patent Offices in preparing the Description.

On the other hand, it can be said that the presence of differences in legal regulations and their application among the Trilateral Patent Offices poses not a small burden on the Applicant. Further-

more, it would be even more troublesome for the Applicant from the viewpoints of patent right utilization and patent management in the event of the emergence of varied scopes of patent right due to the different degrees of rigorousness in the judgments of violations of description requirements among the Trilateral Patent Offices.

Therefore, it is hoped that early harmonization be achieved with regard to the handling of description requirements so as to lessen the burdens on the Applicant.

Notes

1) Document Published by the Japanese Patent Office: A comparison of examination practices among the Trilateral Patent Offices / case study on description requirements (in Japanese) (title of the original document: Comparative Study on Hypothetical/Real Cases: Requirement for Disclosure and Claims), published in June 2008. (http://www.jpo.go.jp/torikkumi/kokusai/kokusai3/pdf/sinsa_jitumu_3kyoku/kisai_honbun.pdf., accessed on March 22, 2013)
2) The Third Subcommittee in the First Patent Committee: A discussion of Japanese, American, European, Chinese, and Korean judgments concerning description requirements for the Description, etc. (in Japanese). JIPA Newsletter Vol. 58, No. 8 (2008), pp. 1019-1031.
3) The Second Subcommittee, the First Patent Committee: Comparison of judgments concerning description requirements among responding families on the basis of US court decisions and examinations (in Japanese). JIPA Newsletter Vol. 59, No. 12 (2009), pp. 1615-1629.
4) The Second Subcommittee in the First Patent Committee: Comparison of judgments concerning description requirements among responding families on the basis of European appeal/trial decisions (in Japanese). JIPA Newsletter Vol. 60, No. 10 (2010), pp. 1633-1650.
5) Fiscal 2007 JPO Industrial Property Issue Research Report: Survey of patent examination practice (description requirements)—An investigational study of description requirements in the field of biotechnology—, pp. 173-201. (http://www.jpo.go.jp/shiryou/toushin/chousa/pdf/zaisanken/1904bio_honpen.pdf., accessed on March 22, 2013)
6) European Commission: Summaries of contributions to the Public Consultation on: “The future of EU Japan trade and economic relations,” p.1. (http://www.jetro.go.jp/world/europe/jp/pdf/20110223.pdf, accessed on March 22, 2013)
7) In 2011 “gyo-ke” (high court administrative litigation case, first trial) Case

Nos. 10146 and 10147, for example, it was stated, "For product inventions, a specific description of the method for producing the product should be specifically described in the Description; however, it can be judged that the above-described enablement requirements are fulfilled, even in the absence of such a description, provided that those skilled in the art are able to produce the product on the basis of common general technical knowledge as of the filing."

8) The Third Subcommittee in the Second Patent Committee: "A comparison of judgments concerning description requirements for the Description, etc., by the Japanese Patent Office and law courts" (in Japanese). JIPA Newsletter Vol. 61, No. 8 (2011), pp. 1133-1149.

9) In 1990 "gyo-ke" Case No. 243, for example, it was stated, "It is commonly recognized by those skilled in the art that it is generally difficult to predict the utility of a chemical substance invention merely from the chemical structure thereof, which structure cannot be revealed without testing, and this is a fact that is prominent to the present court of justice. Therefore, to know the utility of the chemical substance invention, it is necessary to demonstrate the utility by making an actual test, or for those skilled in the art to be able to recognize the utility from results of the test."

10) A.I.P.P.I., Vol. 58, No. 1 (2013), pp. 6-21.

11) In 2009 "gyo-ke" Case No. 10033, for example, the Intellectual Property High Court stated, "The trial decision in the reason thereof says, 'in a use invention for a pharmaceutical, […] for an invention seeking a patent grant to be recognized as being described in the detailed explanation of the invention, it is necessary that the utility of the use be supported by providing pharmacological data or an equivalent in the detailed explanation of the invention' (Written Trial Decision page 2, lines 22-29). It cannot be denied that the same statement applies in some cases in relation to the premise for judging the fulfillment of requirements in Article 36(4)(i) of the Patent Act in light of the gist of the term (i)." Even so, the Intellectual Property High Court also stated, "the portion of the trial decision that the statement in the Scope of Claims does not fulfill the requirements specified in Article 36(6)(i) of the Patent Act unless the Scope of Claims is described in the detailed explanation of the invention in a way such that 'the utility of the use is supported by providing pharmacological data or an equivalent' is not always applicable; and given the judgment of a violation of Article 36(6)(i) of the Patent Act with this

portion as the only reason, there should be a reasoning failure unless such special circumstances exist"

12) Sueyoshi T: Significance of the separate existence of enablement requirements and support requirements (in Japanese). JIPA Newsletter Vol. 63, No. 3 (2013), pp. 311-322.

13) In the greater consultation justice for what is called the polarizing film case [2005 "gyo-ke" Case No. 10042], it was stated, "It should be said to constitute a violation of the gist of the patent system (a patent is not granted for an invention unless the invention is to be published, and is unacceptable) to expand or generalize the content disclosed in the detailed explanation of the invention in an attempt to fulfill support requirements for the Description by submitting experimental data after filing the application so as to supplement the content outside the Description, while no examples are disclosed in the detailed explanation of the invention to the extent that allows those skilled in the art to recognize the resolvability of the problem of the invention, so 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 common general knowledge as of the filing of the application in this case," ruling out the assertion of fulfillment of support requirements by the ex post addition of experimental data.

14) On the other hand, in 2007 "gyo-ke" Case No. 10131, for example, the applicant's assertion of fulfillment of enablement requirements by the submission of a certificate of experimental results was accepted.

15) In 2009 "gyo-ke" Case No. 10434, for example, it was stated, "In interpreting Article 36(6)(ii) of the Patent Act, it is unacceptable to require that any technical significance in relation to the functions, characteristics, problems to be solved, or action pertaining to the invention be shown in the Scope of Claims," on the concept "While Article 36(6)(ii) of the Patent Act says with regard to the description of the Scope of Claims, 'it is necessary that the scope of the claimed invention be clear,' the gist of term (ii) is essentially expressed in this statement, and it is not required to describe other matters, such as functions, characteristics, problems to be solved, or action, pertaining to the invention."

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